October 17, 2008

Steve Phurrough, MD, MPA
Director
Coverage and Analysis Group
Centers for Medicare & Medicaid
7500 Security Blvd, Mail Stop
Baltimore, MD  21244 C1-09-06

Re:  NCA for Positron Emission Tomography (FDG) for Solid Tumors (CAG 00181R)

Dear Dr. Phurrough:

We are writing in response to the Centers for Medicare & Medicaid Services’ (CMS) request for additional comments regarding whether its current framework of cancer-by-cancer coverage for oncologic FDG-PET imaging could be replaced by an omnibus framework. This letter is submitted jointly on behalf of the National Oncologic PET Registry (NOPR) Investigators, the American College of Radiology (ACR), the Academy of Molecular Imaging (AMI), the American Society for Therapeutic Radiology and Oncology (ASTRO), and the Society of Nuclear Medicine (SNM). These groups collectively are composed of clinicians, academicians, researchers and nuclear medicine providers utilizing molecular imaging technologies, including integrated positron emission tomography/computed tomography (PET/CT). We represent tens of thousands of physicians, providers, and patients with regard to this lifesaving technology, and have worked closely with CMS over the past three years to increase beneficiary access to PET/CT through the development of the National Oncologic PET Registry (NOPR).

We believe it is both clinically appropriate and practical for CMS to adopt a comprehensive omnibus cancer coverage framework for PET. During the past two years, Medicare beneficiaries with cancer participating in the NOPR have benefited from better-informed clinical management. Patients with less-common cancers included in the NOPR comprise about 10% of the Medicare population imaged by PET in 2006-2008. Based on the data from the NOPR and the totality of clinical and scientific publications on PET, we strongly support an effort by CMS to update and modernize the current PET NCD policy to allow for the coverage of PET for cancer diagnosis, staging, and restaging (including detection of suspected recurrence).
I. Summary

A revised approach to cancer coverage is supported both by data CMS has obtained under NOPR and by the peer-reviewed literature. Such a revised approach offers four key advantages: 1) it incorporates current non-coverage decisions; 2) it provides clinically appropriate coverage for additional less-common cancers; 3) it simplifies the language of the existing NCD; and 4) it provides CMS with the opportunity to introduce additional safeguards and features that ensure clinical appropriateness of utilization. Based on the omnibus cancer approach, we have drafted a model comprehensive coverage policy, which is provided in Appendix A. This policy includes the following safeguards and features:

**Requiring a clear record of the clinical decision in question.** By requiring the use of a brief, straightforward request form (such as a modified version of that used under NOPR), CMS would provide a clear basis for medical review, require targeted use of PET imaging, and ensure clear and uniform context for the interpreting physician. The criteria for medical need should be indicated by the physician in the patient’s medical record; these criteria should include elements such as the type of suspected cancer, the reason for the scan (diagnosis, staging, restaging, etc.), and whether the scan would alter the current course of management.

**Providing additional guidance on appropriate usage.** We suggest CMS consider using the new NCD to provide more detailed guidance for clinical situations, such as surveillance, where PET coverage is not currently established as useful. For instance, CMS should work closely with the imaging community in providing coverage guidance for scenarios where FDG-PET/CT has limited accuracy related to radiopharmaceutical accumulation (e.g., within the renal pelvis and bladder).

**Requiring accreditation or experience requirements.** Professional requirements are already included in the current NCDs (“providers are qualified to perform and interpret scans”), and the implementation of MIPPA (the Medicare Improvements for Patients and Providers Act of 2008) will mandate additional specific requirements. Requiring statements of necessary experience will substantially help resolve CMS’s concern that clinically uninformed use of PET imaging might occur.

**Continuing coverage under NOPR for therapeutic monitoring.** We recommend that CMS undertake no change at this time in the NOPR-based coverage of therapy monitoring, because we believe that support of additional research in this area will both provide significant benefits to Medicare beneficiaries and provide important information that will improve therapy monitoring nationally.

**Limiting newly granted coverage for body FDG-PET imaging to PET/CT scanners.** CMS should consider whether new coverage for body imaging (granted beyond the legacy coverage as of 2005) should be limited to PET/CT scanners. Such limits are appropriate because almost all cases in the NOPR were studied...
with PET/CT scanners, most recent literature is based on PET/CT scans, and PET/CT improves the accuracy of PET-based evaluations. Moreover, such a restriction will create few (if any) additional administrative burdens, since PET/CT scanners already use a distinct CPT code set. (There is only one PET code for brain-only scans and we do not suggest CMS consider any PET/CT condition for brain scans.)

II. Background: CMS Coverage of PET for Cancer

Clinical use of PET scanning for cancer patient care began in the 1980s, when scanners were few and lesion detection was less reliable than it is today. Medicare coverage of PET began ten years ago, in 1998, with coverage for the evaluation (i.e., diagnosis) of solitary pulmonary nodules and coverage for the staging of non-small-cell lung cancer. Since 2001, CMS has granted year-by-year changes in coverage for a wide spectrum of biologically diverse cancers, providing coverage simultaneously for diagnosis, staging, and restaging. Moreover, where CMS initially provided limited coverage (e.g. for colorectal cancer or for lymphoma), coverage was usually revised to include these three indications (diagnosis, staging, and restaging.) These coverage policies reflect a determination that, across a broad range of common cancers, PET is more accurate in aggregate than CT or MRI scanning alone (although there are scenarios where both of these techniques are valuable for detection of local disease extent and metastasis to specific organs/anatomic locations). For a historical table of progressive Medicare coverage, see Appendix B.

The CMS coverage policy has been conservative and prudent. As such, PET coverage has always been tied (through the diagnosis/staging/restaging definitions) to individual cases of medical necessity based on clinical judgment of the referring physician, armed with all available information about the patient’s disease at that point in time. For example, staging PET scans are covered only when a “conventional” (CT/MRI) evaluation is inadequate for decision-making, or when conventional imaging is less likely to be determinative than a PET scan, and when the information sought is essential for the patient’s particular management decision. Similar criteria govern the coverage of PET for diagnostic and restaging purposes.

III. CMS Coverage with Evidence Development

a. Coverage with Evidence Development and NOPR

In January 2005, CMS initiated coverage of less-common cancers under its Coverage with Evidence Development (CED) policy. Under CED, CMS grants coverage for previously non-covered medical procedures in order to gather evidence about effectiveness. CED is only authorized when CMS is confident that the medical care to be provided is safe for clinical use in the management of Medicare patients. The number of PET scans performed under the CED program represents an incremental increase of only about 10% of the total for the currently covered, more common cancers such as breast, colorectal and lung
cancers. As of September 30, 2008, over 100,000 scans have been performed with data collection under this program.

The National Oncologic PET Registry (NOPR) was created as part of the CED policy on PET, funded entirely by user fees, and has become a collaborative data collection effort that has received broad support from both oncologists and the nuclear medicine community. One major publication using NOPR data has already appeared in print (Hillner et al. (2008)), two more are accepted and in press, and others are in preparation for submission. Additionally, NOPR’s executive team now receives requests from investigators planning additional studies that will combine CMS claims data and NOPR data.

The NOPR CED has produced two striking and important findings. First, evaluation of the NOPR data has shown that, in 36% of cases, use of PET resulted in a major change in management.1 Second, the NOPR data reveal that PET scans covered by NOPR change clinical management decisions just as frequently for less-common cancers as they do for more common and longer-studied cancers. There are also a number of reasons why the NOPR data can be relied on for CMS decision-making. The data are representative; the initial published results spanned nearly 23,000 Medicare patients across 80% of the PET centers in the US. The data are current, having been collected over the past two years. And the data are externally consistent, as the percent change in management closely parallels that of other PET studies in more tightly controlled settings.2

While no outcome metric is perfect, change-in-management has many very important features as a summary metric.3 First and foremost, without changes in management, diagnostic testing would be pointless. The maximum possible change (assuming two-way decisions) is 50%. Thus, the 36% change in management found in analysis of the first-year NOPR cohort is a substantial figure.

Second, the use of clinician management decisions as an endpoint assumes that the treatments chosen through these patient management decisions are clinically useful. This has been the case for the cancers for which PET has been covered thus far (for example, curative surgery for localized lung cancer; FDA-approved therapies for recurrent breast or colon cancer, etc), where subsequent studies have shown a positive impact upon patient outcome (Wiering et al. (2008)); Gulenchyn et al. (2008)).4 Based upon these results, we

---

are confident that this principle can be extended to other cancers, many of which are uncommon and not amenable to trials that use patient outcome as an endpoint for the impact of a diagnostic test like FDG-PET/CT.\(^5\)

Third, the diagnostic reports themselves must be accurate. Although it is legitimate to inquire as to whether the diagnostic reports are a welter of false-positive and false-negative findings that mislead therapy and decrease the quality of care, this is highly unlikely with PET/CT scans for two reasons. Research has consistently found PET/CT to be more accurate than CT or MRI studies alone. And PET/CT scans, now used for most studies in the NOPR cohort, are more accurate than conventional PET scans on which Medicare and other payors based older coverage decisions (i.e., from 1999-2004).\(^6\) Smaller studies of the cancers included in the NOPR cohort also supported the accuracy of FDG-PET/CT (see footnote 5). In this regard, two points are worth emphasizing:

- First, the systematic review of PET commissioned by CMS (McEwan & Gulenchyn, 2008) found overall favorable results for the accuracy of PET/CT scanning in the vast majority of studies.\(^7\) There has been a clear trend to greater accuracy, particularly if PET/CT accuracy studies are compared to 1990s studies of conventional PET.

- Second, when PET/CT has been directly compared (in research settings) by presentation of PET, CT, and PET/CT images to the interpreting physicians, accuracy rises measurably with PET/CT.\(^8\) These results are not considered "primary clinical research" and were excluded for the purpose of the technology assessment in the systematic review. However, the findings are both realistic and

---


very important. Presenting radiologists or pathologists with a series of images or slides to measure accuracy or to measure interobserver variation is a realistic experiment. It is reasonable to conclude that the overall accuracy of PET/CT today is higher than that of conventional PET in use when the initial coverage decisions were issued in the 1990s and early 2000s.

Pragmatic studies, such as NOPR, do not provide all the assurances of controlled trials that use more rigorous outcomes such as patient survival. But important studies in the Medicare population, using data from actual ongoing care, will usually closely track to smaller and more rigorous studies absent significant biases. This has been the case for other cancers such as lung cancer and colorectal cancer for which prior coverage exists.

b. The value of NOPR in the clinical context: Palliative care

NOPR has now provided a unique window into the actual clinical usage of PET scans via the treatment decisions for tens of thousands of Medicare’s cancer patients. Indeed, because of the NOPR data collection protocol, an almost real-time level of insight is available for “rare cancers”. Before PET imaging, 14.3% of patients in the NOPR cohort were under consideration for palliative care (and PET imaging was considered clinically needed); after PET imaging, almost one-third of these patients had a management change and 11% were shifted to a curative protocol. Conversely, of the 19.5% of patients considered for a curative protocol pre-PET, nearly half were shifted to a less-aggressive protocol (including one-fourth to palliative care) after PET imaging.

The importance of these clinical decisions for Medicare’s cancer patients and their physicians has probably been underweighted in previous CMS PET coverage reviews. For example, in Medicare’s coverage review of thyroid studies, PET was found to have substantial prognostic value, but CMS opined that imaging to clarify “prognosis” was not a covered clinical benefit under Medicare. Prognosis is intimately related to palliative management decisions as well as the statutory hospice benefit, and CMS is the only US insurer to follow virtually every beneficiary until his or her death (for which cancer is the second-leading cause).

IV. Systematic Review Methodologies Misjudge the Clinical Usefulness of PET

McEwan and Gulenchyn (2008) undertook a systematic review of clinical PET research from 2004 to early 2008. The systematic review method follows an approach to evidence-based medicine that was developed over two decades in the context of

---


10 After receiving a request in 2002 to review published data on the prognostic accuracy of PET scans for the management of Medicare patients with thyroid cancer, CMS answered flatly that “[The proposed clinical scenario, cancer prognosis] is not reasonable and necessary and was not addressed.” See Decision Memo, CAG-00095N, April 16, 2003.

assessment of therapeutic trials. However, some of the systematic review methodologies have limited utility when applied to diagnostic tests, and particularly to certain clinically important aspects of PET imaging in cancer care.

a. Review methodology versus clinical utility (1): Bias toward irrelevant study criteria

First, the quality of studies is “highly rated” in the systematic review paradigm only when such studies involve either randomly selected patients (as in a randomized clinical trial) or, second-best, an unselected series of patients. Neither rule is realistic for PET imaging in oncology. As CMS’s own coverage guidelines, and the guidance of associations and other insurers repeatedly demonstrate, PET imaging is used to contribute to the differential diagnosis on which hinge patient-specific clinical decisions. These situations, where PET is most useful, are not randomly distributed among patients, nor do they fall in a series. On the other hand, any report presenting a series of clinical encounters (e.g., “PET scanning was judged useful in 80% of cases, when ten of 100 cancer patients were referred for PET scanning”) falls outside the scope of controlled reviews, even though the group reflects both clinical usage and clinical reality. As Sackett wrote in 1996, “evidence based medicine means integrating individual clinical experience with the best available external clinical evidence.”

b. Review methodology versus clinical utility (2): Policy should not require trials that are unethical; example of cervical cancer

Diagnostic tests do not directly affect health. As CMS itself has stated, “[a] diagnostic test affects health outcomes through changes in disease management brought about by physician actions taken in response to test results. Such actions may include decisions to treat or withhold treatment, to choose one treatment modality over another, or to choose a different dose or duration of the same treatment.” In a randomized controlled trial for a therapeutic intervention, one may argue the validity of the endpoint (e.g., biomarker, quality of life, or survival). But the change in the endpoint between groups is real if it is statistically significant and it can be assumed that confounding factors other than the intervention have been randomized away. If there is a difference between therapy and control, there is a difference in the patient status used as an endpoint.

In contrast, it is much more difficult to harness the results of a diagnostic test (e.g., accuracy) directly to long-term clinical outcomes. This is particularly true for survival,

---


16 CMS Coverage Decision 00394N.
because the patients in each arm (receiving or not receiving PET) must be locked into fixed therapy regimens, including treatment on relapse, and followed until death. A PET study with clinical outcome data is as large and costly as a drug clinical trial, because—in effect—it appends a trial of clinical therapy.

CMS itself has directly faced this dilemma. In its 2004 review of cervical cancer coverage for PET, CMS acknowledged that PET imaging improved the early detection of recurrent cancer but stated it was not demonstrated that earlier recurrent cancer diagnosis “improved net health outcomes.”\textsuperscript{17} If coverage is awaiting a clinical trial that directly assesses the value of treating recurrent cancer after diagnosis, the trial would be remarkable. For example, no IRB would ever approve a study in which PET/CT was used to identify 200 patients with recurrent disease, followed by a randomized distribution of half of these 200 with recurrent cancer to a “no treatment” arm. The odds of equipoise must be nearly 50% (range, 40-60%) for IRB approval or patient participation, based on empirical research.\textsuperscript{18} The existing data violate equipoise (recurrent cancer is found; there is FDA-approved and effective therapy for it).

In short, it is fair for researchers to ask whether earlier diagnosis of recurrence will be of benefit. But it is not fair to require a trial where diagnosed, recurrent cancer patients would be randomized to an arm that withholds therapy. When faced with a situation that is incompatible with an RCT, clinical reasoning must prevail rather than awaiting an RCT.\textsuperscript{19} For example, the range of mainstream treatments for most cancers is well understood (surgery for unilateral lung cancer; radiation for bilateral spread; palliation in certain other circumstances; chemotherapy for recurrent breast cancer, etc.) and decision-making often depends on accurate anatomic information. There is little reason to believe that deferral of already approved and already covered therapies improves outcomes.

Earlier trials did use an explicit randomized assignment to PET and non-PET imaging tracks, with improved outcome for the PET-based management plans.\textsuperscript{20} There is a real issue in that it is unclear how long clinical equipoise allows continuation of such trials.

V. Comprehensive PET Coverage

a. NOPR, PET/CT, and Qualified Providers

PET/CT has been a major advance in allowing accurate diagnosis of real disease, as shown by sensitivity/specificity results, which have risen steadily from the 1980s to the 1990s to

\textsuperscript{17} CMS Coverage Decision 00181N, “…it is unclear whether improved early diagnosis of extra-pelvic recurrent cervical cancer leads to improved patient outcomes.”


the 2000s. As diagnosticians, we daily see images where the CT and the PET alone are ambiguous but the PET/CT superimposition is adequate for diagnostic certainty. PET resolves the tumor status in ambiguous enlarged nodes seen on CT, and CT localizes FDG-avid foci to pathologic lesions or sites of physiologic tracer uptake.

We do not propose limiting coverage to PET/CT for body imaging that was covered based on research using PET scans alone (in most cases).

However, nearly all the cases analyzed under NOPR were studied with PET/CT (85%). Therefore, a crosswalk to coverage of PET/CT in these cancers is sound. The prevalence of PET/CT has been easy to assess because PET and PET/CT have distinct CPT codes and slightly different RVU valuations. Under the OPPS and the corresponding DRA crosswalk there is little difference or no difference at all to CMS in its payment for higher-resolution PET/CT studies in comparison to single-modality PET studies.

Note, however, that we do recommend allowing coverage of conventional PET, in addition to PET/CT, (using CPT code 78608 in either case) for FDG imaging of brain tumors, in accordance with the coding recommendations of the ACR and the SNM. When still available, conventional PET is considered equivalent to PET/CT for brain imaging, but results in lower radiation exposure.

On the issue of quality, a large proportion of PET scans are performed in hospitals, where staff are credentialed and quality metrics must be met. Another substantial proportion of PET scans is performed in independent diagnostic testing facilities, where regulations directly require Medicare contractors to implement accreditation standards for both physicians and technical staff (42 CFR § 410.33). We believe that reasonable accreditation or experience standards should apply to office-based PET facilities as well. This requirement would reflect Congressional intent legislated by MIPPA 2008 (CMS plan due by 2010) and private insurers. We believe that burdens will be minimal, as most PET nuclear medicine facilities are managed by board-certified or appropriately trained physicians. CMS has referred to experience in other PET NCDs, such as in its coverage of PET for dementia. In the PET dementia NCD, CMS also describes basic requirements for the ordering physician (“The patient has been evaluated by a physician experienced in the diagnosis and assessment of dementia”). CMS could consider similar language for the ordering physician for PET studies (“The patient has been evaluated by a physician experienced in the diagnosis and assessment of the suspected or proven cancer.”)

b. Clarifying medical necessity guidance and “surveillance”

As CMS considers a new, omnibus consolidation and clarification of its policy for PET imaging, this is a good opportunity to strengthen anti-abuse language in the NCD. We

---

21 See note 7, supra.
23 CR3426, Interpretation by a physician experienced in interpreting such scans; specialist in nuclear medicine, radiology, neurology, or psychiatry.
have no data on how often PET scans have been subject to medical review in the Medicare program. However, new and more precise regulations governing medical review take effect in January 2009 (as 42 CFR § 410.505) and recovery audit contractors will operate nationally in 2009 as well. Therefore, anticipating there will inevitably be enhanced medical review oversight of all providers, it is in the interest of both CMS and the imaging profession to work together to ensure that coverage guidelines for PET be as fair and specific as possible.

Monitoring to determine whether chemotherapy is effective or ineffective is currently covered under NOPR. However, we are unaware of any well-accepted data showing that surveillance imaging with PET (in the absence of symptoms or biochemical evidence of recurrent disease) is linked to improved health outcomes. CMS’s current three coverage indications (diagnosis, staging, and restaging) were not intended to provide coverage for routine ongoing “surveillance” such as annual scans. Still, CMS does cover “restaging” and some clinicians might view these exams as routine annual “restaging.” Imaging for “suspicion” of recurrence is covered, and an asymptomatic patient has a statistical chance of recurrence. CMS should take this opportunity to incorporate a new section that specifically denotes surveillance as non-covered. This will provide an opportunity for public comment and citations to evidence by those who disagree. For example, there is some data that management with routine surveillance scans may be improve health outcomes in colon cancer, and CMS should evaluate this data in light of its coverage standards.

Additionally, it is not possible in general to segregate tumors a priori by FDG avidity. Essentially all tumors are more avid than surrounding tissue, and there is substantial variability among tumors of the same type, for poorly understood reasons. But no coverage decisions at Medicare or other insurers have ever provided restricted coverage within a single tumor type, because there are no a priori biomarkers for FDG-avid tumors. There does not appear to be any biological basis for covering adenocarcinomas of the esophagus, colon and rectum but not similar adenocarcinomas of the stomach and small intestine. NOPR’s data suggest that PET scans, as used by actual clinicians for real patients, are as useful in cancers such as pancreatic cancer as in more common cancers.

In 2004, Medicare approved coverage of PET imaging for treatment monitoring for chemotherapy of breast cancer, and PET may indeed prove useful for treatment monitoring of many other cancers. However, because PET has been used for treatment monitoring only in the last few years, we believe treatment monitoring should remain covered through the NOPR as more data are collected.

VI. Education

Currently the SNM PET/CT Utilization Task Force is developing recommendations for FDG-PET and PET/CT Practice Guidelines in Oncology. In September 2008, the group met to present and review the recommendations and practice guidelines of other professional organizations for the nine indications approved by the Centers for Medicare and Medicaid Services (CMS). The goals of this working group are to: distribute, revise and develop guidelines in oncology; develop educational materials describing best practices; and develop educational activities. This work is intended to serve as an educational tool for referring physicians, as well as nuclear medicine physicians and radiologists, to identify ways to increase appropriate utilization of PET/CT based on medical evidence.

Additionally, the SNM has worked closely with the NOPR on two primary activities to assist with accurate coding advice and second, to provide ongoing education regarding appropriate interpretation and implementation of the CMS national coverage guidelines to the nuclear medicine and PET community. The SNM Coding Corner website has an area devoted to PET education materials including a Q&A section where the public can ask coding questions concerning PET. The SNM continues to work through the Coding and Reimbursement Roadshow to provide a dedicated 1-2 hour segment to common PET coding problems and answering questions from the attendees. Next year, in 2009 the SNM will provide three on-line coding modules one of which will have a special focus on PET and NOPR.

The ACR published two Practice Guidelines regarding FDG-PET for the performance of FDG-PET/CT in oncology and for medical nuclear physics performance monitoring of PET/CT imaging equipment. These practice guidelines represent a policy statement by the ACR which have undergone a thorough consensus process and been subjected to extensive review. The practice guidelines and technical standards address quality patient care addressing safety and effective use of FDG-PET and PET/CT. In an effort to further promote safety and quality care, the ACR offers the Nuclear Medicine/PET Accreditation program. It is designed to offer radiologists and nuclear medicine physicians an opportunity for comprehensive review and evaluation of their Nuclear Medicine/PET facility, personnel qualifications, image quality, equipment, quality control procedures and quality assurance programs through a peer review mechanism.

Additionally, the ACR developed Appropriateness Criteria Guidelines on FDG-PET and PET/CT that are currently under review and will be revised based on recent literature. The ACR Appropriateness Criteria® are evidence-based guidelines to assist referring physicians and other providers in making the most appropriate imaging or treatment decision. By employing these guidelines, providers enhance quality of care and contribute to the most efficacious use of radiology.

Further education is available through the ACR’s continued efforts in PET and PET/CT courses as well as the ACR Education Center. This program highlights hands-on individual workstations, expansive repository of cases and data sets, and a customized
learning environment via the ACR case engine. Coding and billing guidance is available through the ACR’s Nuclear Medicine Coding User’s Guide as well as the ACR Radiology Coding Source™. Additionally, the ACR’s Coding and Nomenclature Committee provides coding consensus information.

VII. Conclusion

We believe that there is strong empirical evidence to support an omnibus cancer framework that would provide for coverage of PET across all oncologic indications for diagnosis, staging, and restaging (including detection of suspected recurrence).

However, we do not believe that there is sufficiently mature NOPR evidence to recommend that CMS end the CED requirements for the coverage of PET for treatment monitoring at this time. We propose to continue using the NOPR to collect data on the value of PET for this purpose, and we will continue to analyze additional data over a longer period.

We look forward to working closely with CMS throughout the reconsideration process, and to providing any additional information that CMS may require.

Sincerely,

/s/ BRUCE E. HILLNER
Bruce E. Hillner, MD
Chair, NOPR Working Group

Harvey L. Neiman, MD, FACR
Executive Director, ACR

Laura I. Thevenot, CAE
Chief Executive Officer, ASTRO

Timothy McCarthy, PhD
President, AMI

Robert W. Atcher, PhD, MBA
President, SNM
APPENDIX A

MODEL POLICY

Positron emission tomography (PET) is a noninvasive diagnostic imaging procedure that assesses the level of metabolic activity and perfusion in various organ systems of the human body. A positron camera is used to produce cross-sectional tomographic images, which are obtained from positron emitting radioactive tracer substances (radiopharmaceuticals) such as 2-[F-18] Fluoro-D-Glucose (FDG), that are administered intravenously to the patient.

In the sections below, “conventional imaging” refers to computed tomography (CT), magnetic resonance imaging (MRI), or ultrasound. Unless otherwise specified, PET scanning refers to single-modality scanning as well as systems which produce registered PET/CT images.

For all uses of PET relating to malignancies the following conditions apply:

A. Diagnosis
PET is covered for cancer diagnosis to help determine if a suspicious lesion is cancer, if the lesion is inaccessible for biopsy, if biopsy is contraindicated, or if biopsy has been done with indeterminate results; to detect a primary tumor in a patient with pathologically proven or strongly suspected metastatic disease of unknown primary origin after negative or indeterminate results of conventional assessment; and to help detect a primary tumor in a patient with a strongly suspected paraneoplastic syndrome after negative or indeterminate results of conventional assessment. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for staging rather than diagnosis. PET is covered for diagnosis only in clinical situations in which:

(1) the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure, or in which
(2) the PET results may assist in avoiding an invasive diagnostic procedure.

B. Staging
PET is covered for staging in clinical situations in which:

(1) it replaces one or more conventional imaging studies when it is expected that conventional study information is insufficient or less adequate for the clinical management of the patient, or
(2) the stage of the cancer remains in doubt or incompletely established following a standard diagnostic workup, including conventional imaging.

For staging to be medically necessary, in either case (1) or (2), the clinical management of the patient will differ depending on the stage of the cancer identified.
C. Restaging
Restaging applies to testing after a course of treatment is completed. PET is covered for restaging:

1. after completion of treatment for the purpose of detecting residual disease,
2. for detecting suspected recurrence or metastasis,
3. to determine the extent of a known recurrence, or
4. if it replaces one or more conventional imaging studies when it is expected that conventional study information is insufficient or less adequate for the clinical management of the patient.

Suspected recurrence means the patient has signs or symptoms or recurrence, including biochemical markers of recurrence. For restaging to be medically necessary, in each case (1) through (4), the clinical management of the patient will differ depending on the stage of the cancer identified.

D. Monitoring
This 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).

E. Noncoverage of screening or surveillance imaging.

PET imaging is not covered for screening purposes, that is, in the absence of signs or symptoms of disease. Surveillance imaging, that is, scheduled or routine imaging to survey for “recurrence” of disease in the absence of specific signs or symptoms, is not covered because it has not been shown to be medically necessary for the management of cancer through the demonstration of improved health outcomes.

NOTE: In the absence of national frequency limitations, contractors should, if necessary, develop frequency requirements on any or all of the covered indications. In general, a diagnostic PET scan (such as to determine tumor biopsy location) suffices for initial staging and is generally performed once. The frequency of restaging will greatly depend on the course of treatment and the number or “cycles” of chemotherapy or other therapies.

COVERAGE GUIDANCE

[We believe that the following two paragraph summarize existing NCD coverage.]

With the exceptions noted immediately following, PET imaging is covered for the following cancers, which were covered prior to January 28, 2005 for diagnosis, staging, or restaging: lung cancer (non small cell); esophageal cancer; colorectal cancer; lymphoma; melanoma; breast cancer; cancers of the head and neck (excluding brain and thyroid). Also covered prior to January 28, 2005 were (1) restaging of follicular-cell thyroid cancer post-thyroidectomy, with with serum thyroglobulin > 10 ng/mg but I-131 body scan negative and (2) initial staging of cervical cancer when CT or MRI imaging is negative for extra-pelvic metastases.
CMS continues specific restrictions in place prior to [DATE], 2009. PET studies solely for diagnosis of breast cancer (i.e., to determine whether a suspicious lesion detected on mammography or physical examination is malignant) or the staging of axillary lymph nodes in breast cancer are non-covered. PET studies solely for the diagnosis of regional lymph nodes in melanoma are not covered.

Unless otherwise specified, effective XX, 2009, covered of other solid tumors such as cervical, ovarian, pancreatic, testicular, and other cancers are covered under the same principles as enumerated above for diagnosis, staging, and restaging.

**MONITORING:**
Monitoring for treatment response is covered outside of evidence development only for breast cancer, when clinically necessary for treatment decisions.

**COVERAGE WITH EVIDENCE DEVELOPMENT:**

[Continuation of NOPR for Monitoring]

**ADDITIONAL RESTRICTIONS:**

[CMS to consider]
APPENDIX B

(From Medicare National Coverage Determinations Manual)

<table>
<thead>
<tr>
<th>Clinical Condition</th>
<th>Effective Date</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solitary Pulmonary Nodules (SPNs)</td>
<td>January 1, 1998</td>
<td>Characterization</td>
</tr>
<tr>
<td>Lung Cancer (Non Small)</td>
<td>January 1, 1998</td>
<td>Initial staging</td>
</tr>
<tr>
<td>Lung Cancer (Non Small)</td>
<td>July 1, 2001</td>
<td>Diagnosis, staging, restaging</td>
</tr>
<tr>
<td>Esophageal Cancer</td>
<td>July 1, 2001</td>
<td>Diagnosis, staging, restaging</td>
</tr>
<tr>
<td>Colorectal Cancer</td>
<td>July 1, 1999</td>
<td>Determining location of tumors if rising CEA level suggests recurrence</td>
</tr>
<tr>
<td>Colorectal Cancer</td>
<td>July 1, 2001</td>
<td>Diagnosis, staging, restaging</td>
</tr>
<tr>
<td>Lymphoma</td>
<td>July 1, 1999</td>
<td>Staging and restaging only when used as alternative to Gallium scan</td>
</tr>
<tr>
<td>Lymphoma</td>
<td>July 1, 2001</td>
<td>Diagnosis, staging and restaging</td>
</tr>
<tr>
<td>Melanoma</td>
<td>July 1, 1999</td>
<td>Evaluating recurrence prior to surgery as alternative to Gallium scan</td>
</tr>
<tr>
<td>Melanoma</td>
<td>July 1, 2001</td>
<td>Diagnosis, staging, restaging; Non-covered for evaluating regional nodes</td>
</tr>
<tr>
<td>Breast Cancer</td>
<td>October 1, 2002</td>
<td>As an adjunct to standard imaging modalities for staging patients with distant metastasis or restaging patients with loco-regional recurrence or metastasis; as an adjunct to standard imaging modalities for monitoring tumor response to treatment for women with locally advanced and metastatic breast cancer when a change in therapy is anticipated</td>
</tr>
<tr>
<td>Head and Neck Cancers (excluding CNS and thyroid)</td>
<td>July 1, 2001</td>
<td>Diagnosis, staging, restaging</td>
</tr>
<tr>
<td>Thyroid Cancer</td>
<td>October 1, 2003</td>
<td>Restaging of recurrent or residual thyroid cancers of follicular cell origin previously treated by thyroidectomy and radioiodine ablation and have a serum thyroglobulin &gt;10ng/ml and negative I-131 whole body scan performed</td>
</tr>
<tr>
<td>---------------</td>
<td>----------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Cervical cancer</td>
<td>April 18, 2005</td>
<td>Initial staging of cervical cancer in patients with no evidence of extrapelvic metastasis on prior CT or MRI</td>
</tr>
</tbody>
</table>