

Medicare Expansion of PET Scans as Cancer Diagnostic Tool

A Review of the Technology and Utilization Implications from the CMS Coverage Decision

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Summary

Recent announcements by the Centers for Medicare and Medicaid Services (CMS) regarding use of positron emission tomography (PET) scans as a cancer diagnostic tool have raised questions about the impact of these coverage decisions on other health plans. This white paper reviews these decisions and the technology, as well as providing utilization and coverage recommendations.

Background

On January 6, 2009, the Centers for Medicare & Medicaid Services proposed a National Coverage Determination (NCD) to expand coverage for initial diagnostic testing with positron emission tomography (PET) for many Medicare beneficiaries who are being treated for cancer. On April 3, 2009, CMS released its decision to change its policy so that all Medicare beneficiaries with certain cancers will be able to receive Medicare coverage for at least one PET scan, as prescribed by their physicians.¹ In the announcement, CMS said:

“The CMS ruling expands the nine currently covered cancers to cover the subsequent treatment strategy, in addition to initial diagnosis under certain circumstances. The nine cancers previously covered are breast, cervical, colorectal, esophageal, head and neck, lymphoma, melanoma, non-small cell lung, and thyroid. Medicare now expands coverage to include ovarian cancer and myeloma, making a total of 11 indications now covered for the initial diagnosis. Its use in planning subsequent treatment strategy for patients with the newly covered cancers (ovarian and melanoma) will only be authorized if part of an approved clinical research study.”

This news, along with recent advances in technology, the continuing evolution of positron emission tomography scanning, and the results of a two-year study called NOPR (The National Oncologic PET Registry), have prompted questions regarding coverage and **increased utilization**. A review of these contributing factors follows.

Technology

The basic technology behind the imaging process has not significantly changed in the past several years. A number of centers have investigated the use of new radio-nuclides but the mainstay remains FDG (fludeoxyglucose).² Nearly all equipment for image acquisition has changed over the past several years, with nearly all capable of obtaining both PET and CT information at the same encounter. National Imaging Associates (NIA) has received authorization requests ranging from one PET code plus contrast to as many as seven codes including PET with contrast, including four (neck/chest/abdomen/pelvis) CT codes with contrast. If your claims system can be set to edit for these codes when submitted together, *consider some form of multiple procedure discount or reduced payment for the technical elements of the combined studies.*

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Proposed CMS Coverage

As noted in the background discussion above, CMS proposed and implemented changes to PET coverage to include all previously covered solid tumors as well as ovarian cancer and myeloma. This is the first significant change since the initial CMS position in 2005.³ The results of the NOPR study appear to have been viewed with favor by CMS and have resulted in this National Coverage Determination. The decision broadens coverage of PET and PET/CT for most oncologic applications, including “subsequent treatment strategy” for the original nine indications and the additional two if the patients and providers are part of an approved clinical trial.⁴

The National Oncologic PET Registry

The National Oncologic PET Registry (NOPR) has been a collaboration of the American College of Radiology Imaging Network (ACRIN), the American College of Radiology (ACR), and the Academy of Molecular Imaging (AMI) along with CMS, to ensure access to Medicare reimbursement for certain types of positron emission tomography scans not currently covered as part of a National Coverage Determination. Participation in the PET Registry by a practitioner/imaging center has allowed the use of PET technology for nearly any oncologic use deemed reasonable by a provider. More specifically, that which was considered “off- label” under current guidelines could be performed/billed/paid under the NOPR program. The facility need only complete the Facility Registration Form and submit it to NOPR Headquarters together with an executed HIPAA Business Associates Agreement (BAA). Subsequent to payment, the facility/provider is required to submit information as to the test’s value. Facilities are charged a \$50 facility registration fee and \$50 for each patient entered on the Registry.

Current/Projected Exposure under Expanded CMS Coverage Decision

Most health plans *and* CMS currently limit coverage to the use of PET for nine clearly defined indications:

- 2000-2005 (SEER 17) cancer data indicates that there are 2.33 new cases of cancer (combined) per thousand in these nine categories *in the commercial population* per year.⁵
- Assuming that there will be a PET performed during the initial work-up and one at the conclusion of treatment, your **current** annual baseline utilization should approximate **2 x 2.33 or about 5/1,000 per annum**. These data are currently borne out by NIA and health plan experience.

With CMS proposed changes:

- The incidence of *CMS covered cancers in the commercial age group* is about 4/1,000 per annum, so the decision to add additional diagnoses would mean that **utilization could double (at most) to approximately 9/1,000**, considerably less than the widened coverage implies.

Additional Considerations

- PET is *solid science* and its use in conjunction with cancer diagnosis and treatment has become a management standard.
- There are an increasing number of hematology/oncology groups across the country that own their own PET scanners, and most of these scanners are of equal or better quality than local hospital equipment. The potential for *self-referral abuse* should be a consideration.
- Expect a considerable number of *attempts to further game the system* beyond the liberal coverage existent today.
 - NIA has experienced many impassioned calls to use PET for all forms of tumors. These requests are typically denied. Many clinical reviewers believe that it is being used as “something to do” arising out of a compassionate desire to give the patient some slim hope. (These requests can be easily identified with the clinical decision support services offered by NIA.)
 - *Close interval follow-up is a real challenge*. We will only approve a follow-up study if there are clearly changing signs and symptoms suggesting deteriorating health status. This really amounts to re-staging as if it were a new tumor. There is considerable creative abuse in the use of follow-up PET imaging, including some suspicious “home-grown” protocols.
- It is NIA policy that we have not (and will not) introduce or authorize any new technology without the expressed consent of the health plan client.

Recommendation

- If the examination qualifies for PET evaluation as an approved tumor type, staging or re-staging and no proximate CT has been done (<4 weeks), NIA will authorize PET and anatomically related CT studies.
- We will authorize PET/CT with fusion for **follow-up one time**.
- We will **not** authorize any PET for “routine surveillance.”

Important Safety Tip

For products that **do not include a pre-authorization process**, consider the fact that a provider can theoretically bill for **non-covered** PET technology under the current non-specific CPT codes. Unless you have tight ICD-9 claim edits, you will likely auto-pay the claim.

For more information about the potential impact of these CMS coverage decisions on your health plan or to learn more about the solutions available, contact your NIA representative or call 1-877-NIA-9762.

1. <http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?from2=viewdecisionmemo.asp&id=218&>. Accessed April 2009.
2. *Safety and Efficacy Study of FLT Radiolabeled Imaging Agent with PET scan in Invasive Breast Cancer.* http://clinicaltrials.gov/ct2/show/NCT00572728?spons=%22Virginia+Commonwealth+University%22&spons_ex=Y&rank=16. Accessed October 2008.
3. *Expanded Coverage for PET Scans for Cervical and Other Cancers, New Coding for PET Scans, and Billing Requirements for PET Scans for Specific Indications of Cervical and Other Cancers* <http://www.cms.hhs.gov/MLNMattersArticles/downloads/mm3741.pdf>. Accessed February 2005, October 2008.
4. <http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?from2=viewdecisionmemo.asp&id=218&>. Accessed April 2009.
5. *National Cancer Institute Surveillance Epidemiology and End Results* <http://seer.cancer.gov/faststats/selections.php?series=cancer>. Accessed October 2008.