

Ivy Ventures Alert

PET/CT Market Grows with CMS Decision to Expand Coverage for Cancer Patients

April 7, 2009

The Centers for Medicare & Medicaid Services (CMS) announced Friday (April 3, 2009) that it will dramatically expand its coverage of FDG PET exams for the diagnosis and treatment of cancer. As a result of this new policy, CMS will now cover FDG PET exams for initial treatment strategy evaluation of patients with nearly all cancer types. CMS also expanded its coverage of FDG PET used in subsequent treatment strategy evaluations for an expanded number of cancer types. Exhibit 1 compares the former coverage framework to the new coverage framework that went into effect on 4/2/09.

CMS replaced its previous four-part framework with a two-part framework: 1) Initial Treatment (formerly Diagnosis & Staging) and 2) Subsequent Treatment (formerly Restaging & Monitoring). For each solid tumor type and coverage scenario, CMS assigns one of the following values:

Cover – All Medicare beneficiaries will be able to receive Medicare coverage for the PET/CT scan.

N/C – Not Covered; Medicare beneficiaries will not be able to receive Medicare coverage for the PET/CT scan.

CED – PET/CT scan coverage requires participation in an approved Coverage with Evidence Development (CED) program and data must be submitted to a clinical registry such as the National Oncologic PET Registry (NOPR). The clinical studies for which CMS provides coverage must answer one of the following questions:

Does the addition of FDG PET imaging lead to:

1. A change in the likelihood of appropriate referrals for palliative care;
2. Improved quality of life; or
3. Improved survival?

The FDG PET clinical studies are designed to collect additional information at the time of the scan to assist in patient management and future CMS coverage decisions.



Exhibit 1: Effect of Coverage Changes on Oncologic Uses of FDG PET

Solid Tumor Type	Former Framework				New Framework	
	Diagnosis	Staging	Restaging	Monitoring	Initial Treatment (Formerly Diagnosis & Staging)	Subsequent Treatment (Formerly Restaging & Monitoring)
Brain	CED	CED	CED	CED	Cover	CED
Breast (female and male)	N/C	2	Cover	Cover	2	Cover
Cervix	CED	Cover	Cover	CED	1 or CED	Cover
Colorectal	Cover	Cover	Cover	CED	Cover	Cover
Esophagus	Cover	Cover	Cover	CED	Cover	Cover
Head & Neck (not thyroid or CNS)	Cover	Cover	Cover	CED	Cover	Cover
Lymphoma	Cover	Cover	Cover	CED	Cover	Cover
Melanoma	Cover	3	Cover	CED	3	Cover
Non-small cell lung	Cover	Cover	Cover	CED	Cover	Cover
Myeloma	NA	NA	NA	NA	Cover	Cover
Ovary	CED	CED	CED	CED	Cover	Cover
Pancreas	CED	CED	CED	CED	Cover	CED
Prostate	CED	CED	CED	CED	N/C	CED
Small cell lung	CED	CED	CED	CED	Cover	CED
Stomach	CED	CED	CED	CED	Cover	CED
Small Intestine	CED	CED	CED	CED	Cover	CED
Bladder	CED	CED	CED	CED	Cover	CED
Liver	CED	CED	CED	CED	Cover	CED
Bone/cartilage	CED	CED	CED	CED	Cover	CED
Uterus	CED	CED	CED	CED	Cover	CED
Gallbladder	CED	CED	CED	CED	Cover	CED
Soft Tissue Sarcoma	CED	CED	CED	CED	Cover	CED
Thyroid	CED	CED	4	CED	Cover	4 or CED
Testes	CED	CED	CED	CED	Cover	CED
All other solid tumors	CED	CED	CED	CED	Cover	CED

- (1) Cervix: Covered for the detection of pre-treatment metastases (i.e., staging) in newly diagnosed cervical cancer subsequent to conventional imaging that is negative for extra-pelvic metastasis. All other uses are CED.
- (2) Breast: Noncovered for diagnosis and/or initial staging of axillary lymph nodes. Covered for initial staging of metastatic disease.
- (3) Melanoma: Noncovered for initial staging of regional lymph nodes. All other uses for initial staging are covered.
- (4) Thyroid: Covered for subsequent treatment strategy of recurrent or residual thyroid cancer of follicular cell origin previously treated by thyroidectomy and radioiodine ablation and have a serum thyroglobulin >10ng/ml and have a negative I-131 whole body scan. All other uses for subsequent treatment strategy are CED.

Opportunity

The CMS decision presents a tremendous opportunity for providers with PET or PET/CT technology to better diagnose and treat cancer for its patients. As outlined in Exhibit 2, CMS added FDG PET coverage for 25 new cancer types for the Initial Treatment of cancer. This decision more than triples the number of cancer types that were previously covered under the CMS guidelines for Initial Treatment using FDG PET. Now, Medicare beneficiaries with nearly all cancer types will be able to receive coverage for at least one PET scan as prescribed by their physician. As is customary, commercial payors are expected to follow suit and adjust their coverage plans to align with CMS.

Exhibit 2: Cancers Covered Under Initial Treatment Guidelines

Cancers Formerly Covered Under Diagnosis & Staging Framework	
Cervix	Lymphoma
Colorectal	Melanoma
Esophagus	Non-small cell lung
Head & Neck (not thyroid or CNS)	
Cancers Added to Initial Treatment Coverage Guidelines	
Brain	Ovary
Myeloma	Pancreas
Small Cell Lung	Soft Tissue Sarcoma
Stomach	Bone/cartilage
Small Intestine	Uterus
Bladder	Gallbladder
Liver	Testes
Thyroid	10 Other Indications

CMS also expanded its coverage of FDG PET usage for the subsequent treatment of ovarian and myeloma cancers, making a total of 11 indications covered for both the initial diagnosis and subsequent treatment strategy.

Exhibit 3: Cancers Covered Under Subsequent Treatment Guidelines

Cancers Formerly Covered Under Restaging & Monitoring Framework	
Breast (female and male) (2)	Head & Neck (not thyroid or CNS)
Cervix	Lymphoma
Colorectal	Melanoma
Esophagus	Non-small cell lung
Thyroid (4)	

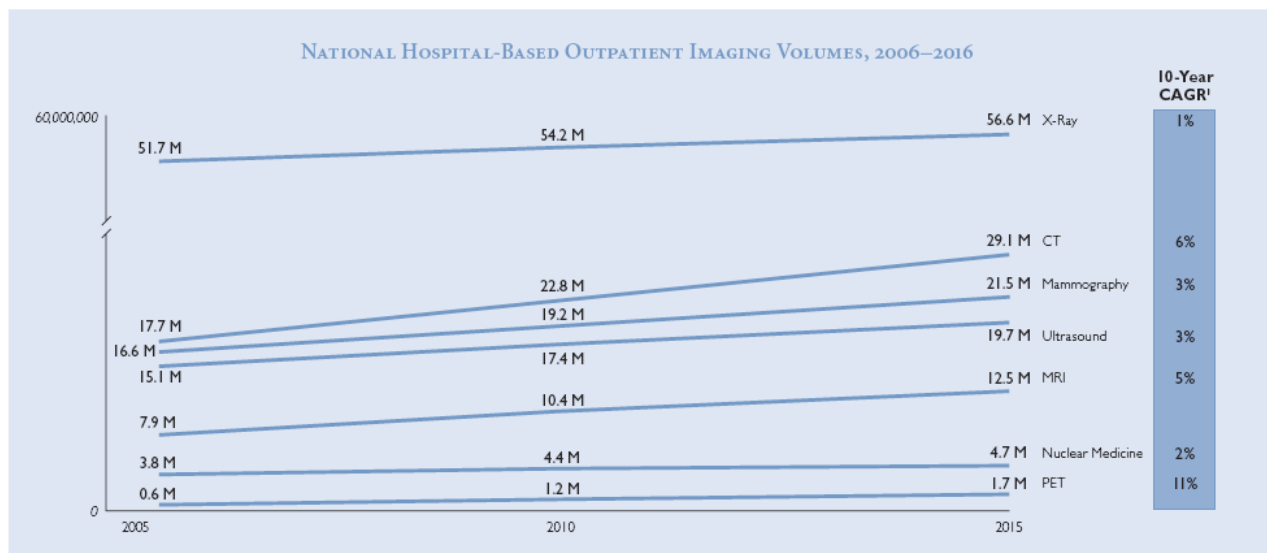


Cancers Added to Subsequent Treatment Coverage Guidelines

Ovary	Myeloma
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PET/CT is the highest reimbursing imaging modality in healthcare with reimbursement ranging from \$1,400-2,500¹ per procedure. It is also the fastest growing modality with a projected 10-year Compounded Annual Growth Rate of 11% according to the Advisory Board and demonstrated on Exhibit 4. Although CT, MRI, and PET/CT all experienced double-digit annual growth over the past decade, the Advisory Board expects only PET/CT will continue its double-digit growth through the next decade.

Exhibit 4: Volume Outlook for Outpatient Imaging²



Source: The Advisory Board

Next Steps

Ivy believes PET/CT will be one of the most significant opportunities for its clients to generate considerable new diagnostic imaging volume in the next few years. We want to develop an individual strategy for your facility to lead your market in this profitable and strategic service.

If you do not currently have PET or PET/CT technology:

- Consider investing in a fixed site or mobile PET/CT unit as a part of your cancer care strategy.
 - Refurbished fixed site PET/CTs can be purchased for as little as \$425,000.

¹ Based on average reimbursements from Ivy Ventures clients across the country.

² *Future of Diagnostic Imaging 2008*. Health Care Advisory Board



- Refurbished mobile PET/CTs cost between \$550,000-\$800,000.
 - Requires a mobile pad and can be transferred to multiple sites throughout the week.
- Lease a PET/CT through a mobile PET/CT provider.
 - Although less lucrative, it allows you to bring PET/CT technology to a service area quickly with no capital investment.

If you already have PET or PET/CT technology:

- Ensure your facility is registered with the National Oncologic PET Registry.
- Develop an updated list of the new covered, non-covered and CED-covered ICD-9 codes and implement them into your computer systems.
- Begin registering CED patients through the new 2009 NOPR database.
- Download and review the new NOPR Operations Manual, Case Report Forms (CRFs), and the slightly revised Patient and Referring Physician Information Sheets from the NOPR website (links provided below).
- Continue to enter data for patients who had their PET performed on or before 4/3/09 in the 2006 NOPR database.
- 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).
- Have targeted marketing materials – including copies of the CMS guidelines – to provide to appropriate referring physicians, especially Oncologists and General Practice physicians.
- Work with Ivy to assess your preparedness and available capacity to accommodate an increase in PET/CT patients.
- Develop a detailed PET/CT sales and marketing plan with Ivy. PET/CT marketing will reach a new and expanded audience of cancer patients and physicians. It is important that we work together to identify these new targets and educate physicians to attract appropriate referrals for PET/CT studies.

Please contact Liana Everaert or Ryan Kokemor at your earliest convenience to set up a conference call or meeting to discuss your PET/CT strategy.

Follow Up Reading

CMS Decision Memo:

<http://www3.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?from2=viewdraftdecisionmemo.asp&id=218&>

New NOPR forms for CED clinical trial patients:

http://www.cancerpetregistry.org/pdf/nopr_opsman.pdf

<http://www.cancerpetregistry.org/forms.htm>

http://www.cancerpetregistry.org/pdf/nopr_patient_informational_sheet.pdf

http://www.cancerpetregistry.org/pdf/nopr_referring_md_sheet.pdf

Aunt Minnie article (free username required):

<http://www.auntminnie.com/index.asp?Sec=sup&Sub=mol&Pag=dis&ItemId=85317>