

Clinical Trials Expand Medicare PET Coverage

While OIG Scrutinizes Billing in 2007

by Daria Niewenhous, Esq., and Christee Goode, Esq.

As Medicare reimbursement for imaging services continues to rise, so do the eyebrows of the Office of Inspector General (OIG) for the Department of Health and Human Services. Utilization of MRI, PET, and CT scans has grown an average of 20 percent per year from 1999-2005. In 2005, Medicare allowed over \$7 billion in charges for these imaging services. This rapid growth sparked the OIG's concern regarding the potential for inappropriate billing that is reflected in the OIG Work Plan for 2007. The OIG announced it will begin to carefully examine the nature and growth of these services. Specifically, the focus is on physicians who bill Medicare more for a scan than the cost to perform the scan, and on operating or testing centers that promote methods for physicians to earn additional income for each referral made. Reportedly, oncologists order the majority of PET scans, averaging as high as 75 to 85 percent of the total scans ordered.

Medicare Coverage Expands

In spite of this "crackdown" on inappropriate billing, CMS recently expanded Medicare coverage in one major area: PET scans. CMS released a new guidance document titled National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development (CED). CED expands PET reimbursement to include a variety of oncologic indications contingent upon provider and patient participation in a CMS-approved clinical trial and registration with the National Oncologic PET Registry (NOPR). The NOPR officially opened in May 2006, and is sponsored by the Academy of Molecular Imaging and managed by the American College of Radiology Imaging Network (ACRIN).

PET scans for cancer diagnosis,

staging, restaging, and monitoring are generally covered in a limited number of cancer indications with a variety of restrictions. CMS previously denied broad coverage of PET procedures due to lack of sufficient data supporting conclusive health outcomes. The CED guidance now expands coverage for PET scans to include several cancers not previously eligible for Medicare reimbursement. Additionally, CED guidance allows coverage of PET for differential diagnosis of dementia and neurodegenerative disease under certain circumstances. CMS' generosity is not entirely altruistic. Practically speaking, the federal government wants evidence on the cost-effectiveness of PET imaging. The agency's objective is to assess the effect of PET scan results on physicians' treatment plans and, hopefully, to achieve broad coverage across all oncologic indications. CMS also hopes to determine if PET scans contribute to the effective diagnosis and treatment of mild cognitive impairment or early dementia.


Participants eligible for the NOPR include PET facilities that are approved to bill CMS for either technical or global charges and Medicare beneficiaries referred for PET imaging for cancers not currently reimbursable under Medicare. Procedurally, physicians refer patients to the facility and commit to submitting the pre- and post-PET data requirements. If the patient consents to participation in the research, the facility registers the patient in the NOPR, and after receiving confirmation from the NOPR, the referring physician submits the pre-PET form to the facility. The facility sends the PET report to the physician following the PET scan, and the referring physician is sent a post-PET form, which must be completed and

returned to the PET facility and entered into the NOPR database within 30 days of the PET scan. After all case data are entered, the facility bills CMS for the study. As of November 2006, more than 1,300 PET facilities have registered with the NOPR and more than 15,000 PET scans were performed that were eligible for CMS reimbursement under the CED methodology.

NOPR also applies to inpatients' PET scans, with the technical charge covered by the DRG payment to the hospital. Inclusion of the patient in the NOPR is required for the professional component reimbursement.

A Word to the Wise

Participation in the CED initiative is highly regulated. Given the OIG's expressed concern regarding inappropriate billing, don't walk blindly into arrangements that promise seemingly glowing opportunities for reimbursements. Physicians are reimbursed for the time spent completing case report forms. NOPR has expressed concerns that such payment to physicians could implicate federal and state anti-kickback laws and could compromise the integrity of the NOPR. Such payment arrangements should be carefully structured to ensure compliance with applicable law.

Oncology practitioners who currently participate, or are considering participating, in the NOPR should carefully review the responsibilities for participating practitioners to maximize Medicare eligibility and to ensure compliance with federal and state laws. 

Daria Niewenhous, Esq., and Christee Goode, Esq., are with the Boston, Mass., office of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.