CMS Details PET Coverage; Claims Processing Begins for New Indications

On April 4, the Centers for Medicare & Medicaid Services (CMS) issued a set of memoranda outlining revisions to the National Coverage Determinations (NCDs) on PET imaging for brain, cervical, ovarian, pancreatic, small cell lung, testicular, and other cancers. The original expansion of coverage for PET to a broader range of cancers was announced in November 2004. In that announcement, CMS said that ^{18}F-FDG PET imaging would be "reasonable and necessary" in the newly expanded indications only when the provider is participating in, and patients are offered enrollment in, 1 of 3 types of prospective clinical studies: (1) a clinical trial of ^{18}F-FDG PET that meets the requirements of the Food and Drug Administration category B investigational device exemption; (2) a clinical trial consistent with the evidentiary requirements for National Coverage Analyses and meeting specific quality standards; or (3) an ^{18}F-FDG PET registry that is designed to provide additional information on the diagnostic accuracy and clinical utility of PET for diagnosis, staging, restaging, and/or monitoring of 1 or more cancers.

In the April 4 memoranda, CMS clarified the types of cancers covered with and without the clinical trials or registry requirement. With this clarification and Medicare carrier claims processing systems readied, billing for the new indications could begin on April 18. Claims for any of the NCD-specified PET examinations performed between January 28 and April 17 may be submitted retroactively.

CMS also announced that it will notify Medicare providers and beneficiaries through the *Federal Register* and the CMS Coverage Web site (www.cms.gov/coverage) as more information on this evidence-based coverage develops. CMS also plans later this year to incorporate into its Web site data on the location and availability of PET centers participating in approved clinical trials or registries.

The following revisions were included in NCDs issued by CMS between April 1 and 5:

- NCD for PET (FDG) for All Other Cancer Indications Not Previously Specified (220.6.15)
  Covered only when providers are participating in, and patients are enrolled in, an approved FDG PET clinical study, or an FDG PET clinical trial meeting FDA category B IDE exemption status. Effective date: 1/28/05. Implementation date: 4/18/05.
- NCD for PET (FDG) for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung, and Testicular Cancers (220.6.14)
  Covered as an adjunct test for detection of pre-treatment metastases (i.e., staging) in newly diagnosed cervical cancer subsequent to conventional imaging that is negative for extra-pelvic metastasis. For all remaining indications, covered only when providers are participating in, and patients are enrolled in, an approved FDG PET clinical study, or an FDG PET clinical trial meeting FDA category B IDE exemption status. Effective date: 1/28/05. Implementation date: 4/18/05.
- NCD for PET (FDG) for Refractory Seizures (220.6.9)
  Removed text from PET Scans NCD (220.6) and created a separate NCD. Effective date: 1/28/05. Implementation date: 4/18/05.
- NCD for PET (FDG) for Esophageal Cancer (220.6.3)
  Only covered for monitoring response to treatment for esophageal cancer as "coverage with evidence development". Effective date: 1/28/2005. Implementation date: 04/18/2005.
- NCD for PET for Perfusion of the Heart (220.6.1)
  Removed text from PET Scans NCD (220.6) and created a separate NCD. Effective date: 1/28/05. Implementation date: 4/18/05.

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tegrity: Part 2" (*J Nucl Med Technol.* 2004;32:158–163). The second-place award will go to Stacey A. Ross, CNMT, RT(N), and John P. Seibyl, MD, for "Research Application of Selected ^{123}I-Labeled Neuroreceptor SPECT Imaging Ligands" (*J Nucl Med Technol.* 2004;32:209–214). The third-place award will be given to A. Robert Schleipman, MA, RT, CNMT; Victor H. Gerbaudo, PhD; and Frank P. Castronovo, Jr., PhD, for "Radiation Disaster Response: Preparation and Simulation Experience at an Academic Medical Center" (*J Nucl Med Technol.* 2004;32:22–27).