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MEDICARE PROPOSES EXPANSION OF PET SCANS AS CANCER DIAGNOSTIC TOOL

CMS Seeks Comments on Proposal to Broaden Coverage for Initial Cancer Treatment Planning under Coverage with Evidence Development Framework

The Centers for Medicare & Medicaid Services (CMS) today 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.

A minimally invasive diagnostic imaging procedure, PET uses a radioactive tracer to evaluate glucose metabolism in tumors and in normal tissue. The test may provide important clinical information to guide the initial treatment approach for many tumors. This additional information may help physicians to distinguish benign from cancerous lesions and better determine the extent of a tumor's growth or metastasis.

Under Coverage with Evidence Development (CED) program, CMS had issued a national coverage determination in 2005 that tied Medicare coverage of PET scans to the collection of clinical information about the effect of the test on the beneficiary's cancer care. This information was obtained through the National Oncologic PET Registry (NOPR) observational study. Without CED, these tests would not have been covered by Medicare.

The purpose of CED is to develop evidence on the utilization and impact of the item or service evaluated in an NCD, so that Medicare can a) document the appropriateness of use of that item or service in Medicare beneficiaries under current coverage; b) consider future changes in coverage for the item or service; c) generate clinical information that will improve the evidence base on which providers base their recommendations to Medicare beneficiaries regarding the item or service.

The sponsors of NOPR submitted a formal written request to reconsider the 2005 coverage determination to CMS, based on the evidence they had collected and published.

Medicare uses a formal evidence based process when it reconsiders past NCDs. This proposed expansion in coverage is the first time that CMS has reviewed medical evidence arising from its CED program.

“We are pleased with these first results of the Coverage with Evidence Development program and look forward to patients gaining greater access to new technologies while enhancing the evidence physicians use to make treatment recommendations,” said CMS Acting Administrator Kerry Weems.

This proposed decision would remove a significant part of the CED requirement for PET scans in cancer and allow coverage for one PET scan to guide the initial treatment strategy. CED will still be required for PET scans for subsequent treatment strategies, as CMS believes that the current evidence is not adequate to provide coverage for PET scans in guiding subsequent treatment.

CMS proposes some cancer-specific exceptions to these broad requirements, which are listed in the proposed decision memorandum.

CMS will accept public comments on the entire proposed decision through February 5, 2009 and will issue a final national coverage determination in April 2009. CMS invites public comments on its proposed decision, which is available at <http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=218>. Instructions on how to submit comments are found at https://www.cms.hhs.gov/InfoExchange/02_publiccomments.asp.

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