

ABSTRACT/STUDY OVERVIEW

Expanded Medicare Coverage for FDG-PET and Cancers with the National Oncologic PET Registry (NOPR)

From 1998 to 2005 through the National Coverage Decisions (NCD) framework, the Centers for Medicare and Medicaid Services (CMS) considered the use of positron emission tomography (PET) “reasonable and necessary” for nine selected malignancies (i.e. breast, cervix, colorectal, esophagus, head and neck, lymphoma, melanoma, non-small cell lung, and thyroid), and reimbursed for those services. Coverage, however, was restricted to these cancer types, even though it was known that PET scanning could be useful for diagnosing other cancers.

In 2005, the CMS policy “Coverage with Evidence Development” (CED) provided an opportunity for “coverage with study participation” as a strategy for collecting data in areas where current evidence was not sufficient to support a coverage decision.

The National Oncologic PET Registry (NOPR) registry was a prospective, web-based registry of Medicare beneficiaries in all 50 US states. The purpose of the study was to assess how PET scans impacted physician’s intended management. Doctors were asked in each case whether the results of the PET scan were used in decision making. The focus was non-covered cancer indications, including ovary, pancreatic, and prostate cancer. Any PET facility approved to receive CMS reimbursement could participate in the registry and reimbursement was provided only if data were submitted to the registry. Data were collected from the PET facility, the referring physician, and the interpreting physician report.

In the first year of the registry, data were received from more than 1,000 facilities and nearly 23,000 PET cases. The authors defined change in management in terms of treatment, such as surgery, chemotherapy, and non-treatment, including watching, noninvasive imaging, biopsy, and supportive care. Analysis showed that physician’s intended treatment or non-treatment management changed in 36.5% of cases (95% CI 35.9-37.2) and their intended management was 3.4 times more likely to lead to treatment than non-treatment scan (95% CI 3.2-3.6). The authors also evaluated management changes in terms of intended action, with approximately 75% of biopsies avoided in patients with intended biopsies. In almost 9% of intended treatment cases, use of PET scans lead to a major change in the type of treatment.

SUPPORT FOR DECISION-MAKING

What type of decision did the study support? How was the study used?

Based on the initial results from the NOPR, along with additional evidence (i.e. published literature and technology assessment), CMS expanded Medicare coverage for the use of PET in the initial treatment (e.g., diagnosis and staging) of nearly all solid tumor types. In addition, PET use for subsequent treatment evaluations (e.g., restaging and monitoring treatment response) also had an expanded coverage for a number of cancers. This modification in CMS's coverage determination was the first example of linking coverage and generating new evidence within the CED policy.

Were there any clinical trials that also addressed the same topic in the same population? If so, please provide reference (trial name and any key publications).

No. Prior to coverage with evidence development (CED), CMS coverage decisions were made based on a review of the available scientific evidence. In the case of PET, previously published clinical trials lacked generalizability of results to the Medicare population, and outcomes were often measured over a limited follow-up period, making prospective, observational studies desirable to evaluate the treatment effectiveness for Medicare patients.

Publication Reference(s).

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