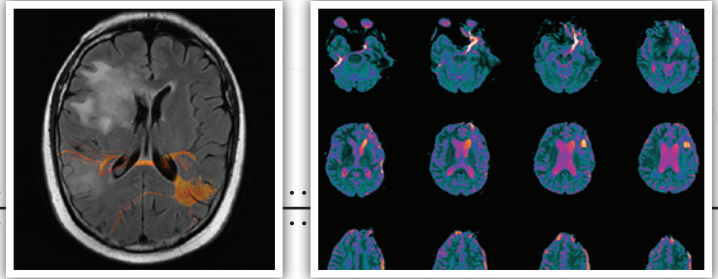


CASE STUDY



National Oncologic PET Registry (NOPR)

NOPR Working Group

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INTRODUCTION

The National Oncologic PET Registry (NOPR) arose in response to a Centers for Medicare and Medicaid Services (CMS) proposal to expand cancer-related coverage of positron emission tomography (PET) using f-18 fluoro deoxy-glucose (FDG). Whereas FDG-PET was CMS-approved for only a limited number of cancers, CMS agreed to conditional coverage of most cancers and related indications for those patients enrolled in a clinical registry evaluating the impact of PET on cancer management. Thus, the NOPR was devised as a prospective registry to collect data on patients undergoing PET for cancers and indications not otherwise covered by CMS. The NOPR provides data on the clinical utility of PET for conditionally covered cancers and indications to help CMS determine whether unconditional coverage is warranted.

Sponsored by the Academy of Molecular Imaging, the NOPR is managed by the American College of Radiology (ACR) through the American College of Radiology Imaging Network. The NOPR is endorsed by the ACR, the American Society for Clinical Oncology and the Society for Nuclear Medicine.

FEATURES

Goals

The primary goal of the Registry is to provide CMS with data on the use of FDG-PET in cancer management to make payment determinations. Physicians' treatment plans are recorded before and after PET imaging to determine the impact of PET in treatment planning decisions.

Facility Registration

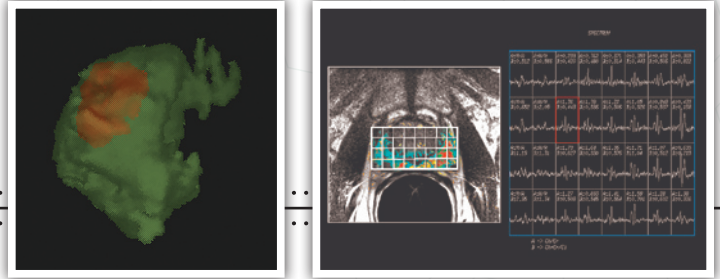
Any PET facility that is approved to bill CMS for either technical or global charges can apply to participate in the NOPR. Interested facilities can register via the Facility Registration tool on the NOPR website, www.cancerpetregistry.org. As of September 30, 2007, there were 1,624 registered PET facilities and data from 50,307 patients registered with NOPR making them eligible for CMS reimbursement.

Patient Eligibility

Medicare beneficiaries (primarily patients at least 65 years old) referred for PET for most oncologic indications not currently reimbursable under Medicare are eligible to participate. Patients may have newly or previously diagnosed cancer. They may be referred for PET to aid in diagnosis, staging, restaging, and/or treatment monitoring.

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Those cancers and indications already reimbursable by Medicare are NOT eligible for entry in the NOPR. Those cancers and indications that are specifically denied Medicare reimbursement are also NOT eligible. The indications link on the website (www.cancerpetregistry.org) provides complete details.

PHYSICIAN RESPONSIBILITY

The referring physician must complete Pre- and Post-PET data collection forms. These properly completed forms represent the critical data being collected by the Registry. Reimbursement for an eligible PET study hinges on the appropriate and timely completion of these forms.

STUDY DESIGN

Registered patients are classified by cancer type and clinical indication for PET. Based on PET results, several different management decisions may occur, such as watchful waiting, noninvasive imaging, biopsy, treatment with curative intent, or treatment with palliative intent. Researchers hope to determine the magnitude of PET's clinical impact prior to data submission to CMS for coverage review for each application of PET for each cancer.

SUMMARY

The NOPR was designed as a prospective clinical registry to obtain conditional CMS coverage of FDG-PET used in an expanded array of cancers and related indications. The Registry has collected data to assess the effect of PET on cancer patient management. The NOPR will provide data on the clinical utility of FDG-PET for conditionally covered cancers and indications to help CMS determine whether coverage of these items is otherwise justified. Initial results of the NOPR have been analyzed and will soon be publicly reported.

ABOUT IMAGE METRIX

As molecular imaging technologies have advanced, the American College of Radiology (ACR) and the American College of Radiology Imaging Network (ACRIN) have been on the forefront of the ability to monitor the action of drug candidates on the human body.

ACR Image Metrix is the result of this heritage and is the premier partner of choice for all aspects of the imaging CRO experience—for pharmaceutical, biotechnology and medical device manufacturers seeking organizational agility in support of healthcare initiatives. A world-class team of physicians and scientists with proven experience employing state-of-the-art technologies to provide complete imaging core lab services in support of efficient clinical trials are able to achieve:

- Smaller clinical trials with fewer patients
- Earlier go/no-go decisions
- Faster regulatory approval
- Shorter time to market