

## **WMIS Welcomes CMS Decision: Expanding Coverage for FDG-PET and Ending NOPR Data**

The Centers for Medicare & Medicaid Services (CMS) released a final decision memorandum concluding that FDG Position Emission Tomography (PET) is nationally covered to guide subsequent management of anti-tumor strategy, and the agency ended the requirement for prospective data collection.

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On June 11, 2013 the Centers for Medicare & Medicaid Services (CMS) released a final decision memorandum concluding that FDG Position Emission Tomography (PET) is nationally covered to guide subsequent management of anti-tumor strategy, and the agency ended the requirement for prospective data collection. The National Oncological PET Registry (NOPR) was developed jointly by the ACR and WMIS as one of the first projects under the Coverage with Evidence Development (CED) program to determine if FDG-PET scans improve patient outcomes in the diagnosis and disease management for the Medicare population. Based upon the clinical and scientific data developed by NOPR and other researchers, in a landmark decision, CMS expanded coverage without data collection for FDG PET for all cancers for indications that CMS labels as “subsequent treatment strategy”, which includes uses more commonly described as treatment monitoring during therapy, restaging after completion of therapy, detection of suspected recurrence (restaging of patients with documented recurrence to plan additional therapy).

In a proposed decision memorandum, issued on March 13, 2013, CMS had limited coverage of subsequent treatment strategy FDG PET to one scan per patient per cancer, with any additional studies at the discretion of regional Medicare contractors. Based on data submitted by the NOPR and public comments from patient advocacy groups and physicians, CMS revised the final decision to cover three FDG-PET scans per patient. Coverage of any additional FDG-PET scans used to guide subsequent treatment strategy can be determined by regional Medicare contractors.

World Molecular Imaging Society played a leading role in the design and management of the National Oncological PET Registry. “WMIS has worked on a collaborative basis with CMS over the past ten years to develop clinical and scientific evidence and data to help patients and physicians. We are happy to have played a central role in one of the first CED projects, and are pleased that CMS recognized the work of NOPR. We hope that the long process of coverage for FDG-PET has laid a foundation for a more streamlined coverage of future oncology imaging agents. .” said Kim Pierce, the Executive Director of WMIS.

Commenting on the final decision, Barry Siegel of Washington University said, "Speaking on behalf of the entire NOPR Working Work, I am gratified at the culmination of our 7-year effort to obtain broader coverage for FDG-PET. The success of our foray into Coverage with Evidence Development speaks to a strong collaborative relationship

with CMS, and we greatly appreciate CMS' responsiveness to the community's input in formulation of the final decision. My only regret is that our colleague Ed Coleman was not able to share this important event with us."

Professor Ed Coleman, a well-recognized PET advocate passed away in 2012.

In the final decision CMS also expanded the number of covered scans for subsequent treatment strategy to three scans and has indicated covering prostate. Dr. Steve Larson of Memorial Sloan-Kettering Cancer Center said "My colleagues and I are very pleased that FDG-PET is recognized by CMS for use in prostate cancer based on the peer reviewed literature and evidence. I think it says something good about the process that despite an initial proposed "non-coverage", upon re-review with additional data, CMS decided that PET FDG was reasonable and necessary for patients with progressing prostate cancer. CMS is to be commended for putting in place a review that was both thorough and fair."

Please note that this decision applies to the FDG-PET registry (NOPR-2009) only. The NaF-PET registry run jointly by ACR-WMIS will continue to collect additional data.

About WMIS:

The World Molecular Imaging Society (WMIS) is an academic and professional society for Molecular Imaging. From leading projects such as PET awareness campaigns and registry management on the clinical side to developing powerful preclinical models and training programs, WMIS is active across the entire spectrum of Molecular Imaging. WMIS is the world's most innovative and leading society in molecular imaging and molecular medicine. With the rise of the molecular imaging industry and the associated research, WMIS is the only organization that is connecting all the dots in the industry and is working to bring all stakeholders together by Smashing the Silos and Leading Innovation Convergence in molecular medicine through imaging; both for practitioners and researchers, who are defining the future of molecular imaging, WMIS enhances the potential and applications of innovation. <http://www.wmis.org>