

MITA PET Coverage Workshop

The Medical Imaging & Technology Alliance (MITA), a Washington-based industry organization, convened a workshop on July 27 and 28 in Baltimore, MD, to consider alternative pathways for Centers for Medicare & Medicaid Services (CMS) coverage decisions for new PET radiopharmaceuticals and imaging procedures. Attendees included representatives of CMS, the Agency for Healthcare Research and Quality, industry, and professional organizations (including SNM). The purpose of the workshop was to identify possible new pathways for CMS coverage of PET imaging.

The rationale for the conference was the need to address the extended period required to approve coverage for oncologic applications of PET imaging and concerns that future beneficial PET radiopharmaceuticals would face similar hurdles. Under the current exclusionary national coverage determination (NCD) process, it can take years to bring these new radiopharmaceuticals into the clinical arena. Once a radiopharmaceutical is approved by the Food and Drug Administration (FDA), CMS typically requires evidence-based data to make a coverage determination for each clinical scenario. For example, oncologic ^{18}F -FDG PET/CT NCDs have been made indication by indication, requiring several years to achieve.

According to Louis Jacques, MD, director of the CMS Coverage and Analysis Group, the CMS NCD process typically takes 6–9 mo. The preferred road to diagnostic coverage is to provide adequate evidence that, compared to alter-

natives, incremental information obtained by new diagnostic technology: (1) changes the physician recommendations; (2) results in changes in therapy; and (3) improves clinically meaningful health outcomes. The more persuasive health outcomes of interest are: (1) longer life and improved function and participation; (2) longer life with arrested decline; (3) significant symptom improvement allowing better function and participation; and/or (4) reduced need for burdensome tests and treatment. In 2006, the National Oncologic PET Registry (NOPR) was created in collaboration with CMS. CMS agreed that coverage for PET would occur by a process known as coverage with evidence development (CED). Data from NOPR led to broader coverage for FDG PET in 2009.

The MITA workshop began with a 4-h brainstorming session. Five possible alternate pathways for coverage determination were identified from this session: (1) reform of NCD to improve responsiveness and timeliness; (2) parallel review of new radiopharmaceuticals by FDA and CMS without extending timelines; (3) coverage by local coverage decision instead of NCD; (4) immediate coverage with relevant conditions and sponsor commitments; and (5) multiple pathways. A full report from the workshop is in progress.

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MOLECULAR IMAGING UPDATE

In Vivo Preclinical Imaging: An Introductory Workshop

Johns Hopkins University (JHU), the University of Virginia, and SNM's Center for Molecular Imaging Innovation and Translation are hosting a preclinical imaging workshop on March 20 and 21 on the JHU campus in Baltimore, MD. The workshop is targeted toward physicians, scientists (including postdoctoral fellows and graduate students), and scientific laboratory professionals interested in using molecular imaging for in vivo biomedical applications. Individuals of all experience levels are welcome. Participants will learn the fundamentals of various small animal imaging modalities. A limited number can attend a half-day session of hands-on training and demonstrations on the afternoon of the second day.

Key topics to be covered include instrumentation, data acquisition and reconstruction, MR/SPECT/PET imaging probes, targets and applications, small animal handling, techniques for imaging infectious disease models, and data analysis. Modalities covered will include MR imaging and MR spectroscopy, PET, SPECT, optical imaging, ultrasound,

x-ray CT, photoacoustic imaging, and additional multimodality imaging.

Speakers will include faculty from JHU and the University of Virginia, as well as industry professionals. They will include: Dimitri Artemov, PhD; Stuart Berr, PhD; Zaver Bhujwala, PhD; Emad Boctor, PhD; Cory Brayton, DVM; Catherine Foss, PhD; Kathy Gabrielson, DVM, PhD; Kristine Glunde, PhD; Mike V. Green, MS; Sanjay Jain, MD; Kimberly Kelly, PhD; Xingde Li, PhD; Ronnie Mease, PhD; Sridhar Nimmagadda, PhD; Martin Pomper, MD, PhD; Sangeeta Ray, PhD; Benjamin Tsui, PhD; Mark Williams, PhD; and Jingyuan Xu, PhD.

To see the complete program or for more information about attending the workshop, visit www.snm.org/pci2012.

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