MedCAC Committee Meeting and USP News

In August the Centers for Medicare & Medicaid Services (CMS) convened a Medicare Evidence Development and Coverage Advisory Committee (MedCAC) meeting to discuss whether Medicare should extend PET reimbursement for the 9 cancer indications currently covered through the National Oncology PET Registry (NOPR): brain, cervical, bladder, small-cell lung, ovarian, testicular, prostate, kidney, and pancreatic cancers. Representatives from SNM, the American College of Radiology (ACR), the American Society for Therapeutic Radiology and Oncology (ASTRO), the Academy of Molecular Imaging (AMI), NOPR, and other cancer advocacy groups attended the meeting in support of broad Medicare coverage across all cancer indications using PET scans.

The meeting took place in response to NOPR's March 2008 request that CMS broaden PET reimbursement across all cancer indications, including the 9 cancers for which Medicare is currently reimbursing. Since 2006, Medicare has covered patients with these 9 cancers only if they were enrolled in the registry.

The meeting included several presentations showing the clinical utility of PET in cancer diagnosis and treatment. NOPR Working Group Chair Bruce Hillner, MD, presented the conclusions of the NOPR registry data, showing that ^{18}F-FDG PET is associated with a 36.5% change in intended management of patients. These findings were published in the *Journal of Clinical Oncology* in March 2008. David Mankoff, MD, PhD, presented an intersocietal consensus statement from SNM, ACR, ASTRO, and AMI on the accuracy and impact of ^{18}F-FDG PET for cancers studied in the NOPR. According to Mankoff, "as clinical trial data continues to support the impact of previously covered indications and NOPR along with other recent trials support FDG PET accuracy and impact for a wide range of other cancers, we recommend that CMS implement broad coverage of FDG PET for cancer diagnosis, staging, and restaging of suspected recurrence."

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The MedCAC panel of 8 members included radiation oncologists, independent medical consultants, and others. At Newsline press time, the official recommendations of the panel had not been released. CMS has stated that it hopes to have a proposed decision memo by January 2009, with an expected completion date in April.

USP General Chapter <797> Update

The SNM Committee on Pharmacopeia, together with the society's Health Policy and Regulatory Affairs staff, has posted answers to frequently asked questions (FAQ) about U.S. Pharmacopeia (USP) General Chapter <797>, *Pharmaceutical Compounding—Sterile Preparations*, in the Government Relations section of the SNM Web site. Questions not answered in the FAQ section may be sent to USP797@snm.org.

SNM has sent a letter to the USP Sterile Compounding Committee discussing issues regarding the use of in vitro ^{99m}Tc-labeled red blood cells prepared with the UltraTag RBC Kit (Covidien, formerly Tyco Healthcare, Mallinckrodt; St. Louis, MO) as it relates to compliance with USP General Chapter <797>. A copy of the letter is available on the SNM Web site at http://interactive.snm.org/index.cfm?PageID=7964.

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