



PET as Part of CMS Effort to Improve Care for Cancer Patients

The Centers for Medicare & Medicaid Services (CMS) announced on November 1 a set of new steps to improve care for cancer patients by “expanding coverage for screening tests and treatments, developing better evidence on which treatments work best for beneficiaries with cancer, and implementing a demonstration program to measure and improve quality of care.” In addition to expanding coverage and trials of “off-label” targeted therapies, the announcement included proposed expanded coverage for PET in cervical cancer and “for studies of PET for diagnosis and staging involving a broad range of additional types of cancer.” CMS also announced a \$300 million nationwide demonstration program open to all oncologists to measure and improve the quality of care provided to Medicare patients. “We are working with the National Cancer Institute, oncologists, and the cancer community to develop better evidence to support the best possible treatment decisions for our beneficiaries,” said CMS Administrator Mark B. McClellan, MD, PhD.

In a draft decision memorandum also released on November 1, CMS outlined in detail the proposed expansion for PET, including the following:

CMS has proposed that there is sufficient evidence to conclude that an FDG PET scan for the detection of pretreatment metastases in newly diagnosed cervical cancer subsequent to negative conventional imaging would be reasonable and necessary, and CMS proposes to issue a national coverage determination (NCD) for this indication.

CMS has proposed that the evidence is sufficient to conclude that an FDG PET scan for staging or detecting recurrent or residual disease in testicular cancer would not be reasonable and necessary, and CMS proposes to issue a national noncoverage determination for this indication.

For all other indications listed in the decision memorandum, CMS proposed that ^{18}F -FDG PET imaging would be “reasonable and necessary” only when the provider is participating in and patients are offered enrollment in 1 of 3 types of prospective clinical studies: (1) a clinical trial of ^{18}F -FDG PET that meets the requirements of Food and Drug Administration (FDA) category B investigational device exemption; (2) a clinical trial consistent with the evidentiary requirements for National Coverage Analyses and meeting specific quality standards; or (3) an ^{18}F -FDG PET registry that is designed to provide additional information on the diagnostic accuracy and clinical utility of PET for diagnosis, staging, restaging, and/or monitoring of 1 or more cancers.

CMS press materials emphasized that these proposed coverage expansions reflect new procedures implemented to more rapidly review scientific evidence for coverage decisions. CMS also announced a national oncology demonstration to evaluate measures of patient well-being in office-based oncology practice, as a basis for addressing quality of life concerns for Medicare beneficiaries with cancer.

A complete copy of the draft memorandum on expanded PET scan coverage and information on providing comments are available at <http://cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=92>.

Centers for Medicare & Medicaid Services

AMA Cites SNM for Educational Excellence

SNM has been recognized by the American Medical Association (AMA) for educational excellence in Current Procedural Terminology (CPT) educational activities and endeavors. The award was presented to members of the SNM Coding and Reimbursement Working Group at the annual meeting of the AMA CPT/Health Care Professionals Advisory Committee on November 5 in Bal Harbor, FL, by Dr. Tracy Gordy, chair of the CPT Editorial Panel.

Accepting the Specialty Society Educational Excellence Award on behalf of the SNM were Gary Dillehay, MD, chair, SNM Coding and Reimbursement Committee; Andrea McGuire, MD, Coding and Reimbursement Committee and Working Group member and CPT Editorial Panel member; Denise Merlino, MBA, CNMT, SNM coding advisor and consultant; and Hugh Cannon, SNM director of public affairs. Kenneth McKusick, MD, SNM CPT advisor and chair of the Nuclear Medicine Ambulatory Payment Classification Task Force, was a key participant in the activities that were recognized by the award but was unable to attend the meeting.

The educational activities for which SNM was cited include a series of coding and reimbursement seminars and educational programs presented by public affairs staff, a number of articles that appeared in SNM publications, such as *Uptake* and *The Journal of Nuclear Medicine Technology*, member information provided on the SNM Web site, and articles provided to external publications such as *Advance*, *Scanner*, the newsletter of the American College of Nuclear Medicine Physicians, and

the American Hospital Association Coding Clinic for Healthcare Common Procedure Coding System.

Society of Nuclear Medicine

Report Shows Growth in PET/CT

An estimated 706,100 clinical PET patient studies were performed in the United States in 2003, according to a report released in mid-November by IMV Medical Information Division (Greenbelt, MD), a marketing and research firm. These studies were performed in 1,500 hospital and non-hospital sites and included PET, PET/CT, mobile PET or hybrid units, and nuclear medicine cameras with coincidence detection. Oncology indications accounted for 93% of PET studies, with cardiology and neurology applications making up most of the remaining 7%.

"PET/CT scanners have quickly become the preferred technology for PET imaging, as the integration of the functional PET images with the anatomical visualization of CT has allowed more accurate and faster diagnosis," said Lorna Young, Senior Director, Market Research at IMV. "While the proportion of PET/CT scanners (vs. PET scanners) installed in 2003 was about 50%, at least 90% of the PET units planned for purchase over the next 3 years will be PET/CT scanners." The report indicates that the PET imaging market is continuing to experience double-digit growth, with studies performed in 2003 increasing 58% from 447,200 patient studies in 2002. However, many sites are still evaluating the extent of their buy-in. Although 1,500 sites offer PET imaging, nearly 900 of these sites use mobile PET or mobile PET/CT, typically for 1–2 days a week, 100 still use gamma cameras with coincidence detection, and slightly more than 500 sites own a fixed PET or PET/CT unit.

The IMV 2003 *PET Census Database* provides comprehensive profiles of more than 80% of the identified PET imaging sites in the

United States. The proprietary database can be licensed or purchased and includes contact and site-specific information about the PET installed base by equipment type and manufacturer, planned equipment purchases, cyclotron installations, and radiopharmaceutical utilization by supplier. For more information about the *PET Census Database and Market Summary Report*, visit the Web site at www.imvlimited.com.

IMV Medical Information Division

SNM/ACNP Provide Formal RDRC Input

SNM and American College of Nuclear Physicians (ACNP) leadership contributed 6 presentations to the Radioactive Drugs for Certain Research Uses meeting of the U.S. Food and Drug Administration (FDA) Radioactive Drug Research Committee (RDRC) on November 16 in Rockville, MD. The public meeting was called by the RDRC staff to solicit public input on the need to modify conditions set forth in 21 CFR 361.1 that ensure the safe use of radioactive drugs for basic research purposes without an Investigational New Drug application. The meeting is part of the FDA outreach to the nuclear medicine community aimed at reenergizing the role of the RDRC.

SNM President Mathew Thakur, PhD, presented the Society's suggestions to the FDA on pharmacology issues. Henry Royal, MD, immediate-past SNM president, presented the Society's views on radiation dose limits for adult subjects and the exclusion of pregnant women from some research studies. Michael Gelfand, MD, an SNM past-president, presented the Society's suggestions for pediatric studies under an RDRC. ACNP/SNM Joint Government Relations Committee Chair Terry Beven, MD, along with Thakur, provided FDA RDRC staff with suggestions from both ACNP and SNM on membership and administrative issues relating to the RDRC.

Society of Nuclear Medicine

Grant Encourages Online NM Training

The U.S. Department of Education announced recently a grant to the University of Arkansas for Medical Sciences and the University of New Mexico (UNM) to expand online training programs for physicians, radiochemists, pharmacists, and technologists working in nuclear medicine throughout the country. The grant, from the Fund for the Improvement of Postsecondary Education, will go to augment an existing distance education program in nuclear pharmacy. The 3-year award amount is \$440,861, for additions to a Web-based curriculum called Nuclear Online Education, which supports problem-based learning and experiential training at local facilities and has a special focus on two topics cited as "of high national significance": nuclear cardiology and PET.

"There are critical shortages of programs and educators to train the number of nuclear medicine health care professionals needed," said Dr. Jeffrey Norenberg, associate professor and chair of radiopharmaceutical sciences at the UNM College of Pharmacy. The Nuclear Online Education partner efforts began in 2001, and 160 students have completed the program. "The project is unique in that it targets institutions that have not fully utilized distance education. It combines distance learning with problem-based learning and training at clinical sites. By doing this, it increases access to highly specialized training programs, minimizes institutional overlap, and maximizes the use of technology, making it an extremely cost-effective method for delivering education." A UNM press release indicated that the partners hope to expand the reach of the online effort to include more than 500 nuclear medicine and allied training programs.

University of New Mexico

2010 WFNMB Set for South Africa

At the meeting of the World Federation of Nuclear Medicine and Biology (WFNMB) in Beijing, China, in October, South Africa was chosen as the host for the 2010 WFNMB Congress, the first time that this event has been held on the African continent. More than 4,000 attendees are expected for the 4-day event. "The South African Society of Nuclear Medicine is proud to host this prestigious event," said Professor Annare Ellmann, chair of the society's bid committee. "Our aim will be to improve the profile of nuclear medicine not only in South Africa but also on the rest of our continent. We shall also encourage the attendance of delegates from all over the world." The meeting presentations and exhibits will be at the Cape Town International Conference Centre, against the dramatic backdrop of Table Mountain. "Cape Town and the Western Cape, with its abundance of natural beauty, modern infrastructure, and world class medical and research institutions, is undoubtedly a fitting place to host the 2010 WFNMB," said Noki Dube, CEO of Cape Town Routes Unlimited.

Plans are already well under way for the 2006 meeting of the WFNMB, October 22–27, in Seoul, Korea. With a theme of "Global Harmonization and New Horizons for Nuclear Medicine," the meeting will foster a "synergistic commitment that will not only encourage constant progress and promotion of nuclear medicine throughout the many regions of the world but will ultimately serve to reduce international heterogeneity in the field," according to an invitational statement from Myung-Chul Lee, MD, WFNMB president. For more information about the WFNMB, see www.wfnmb.org.

World Federation of Nuclear Medicine and Biology

Imaging Residencies and Pregnancy

A study reported at the 2004 Radiological Society of North America meeting in December by a team from Boston University (BU) Medical Center found that only half of the surveyed radiology departments in U.S. medical schools have written policies addressing concerns about pregnancy and work processes in their departments, and a majority of respondents would support a national standard recommendation. "Pregnancy in residency even today has the ability to elicit significant anxiety in program directors," said Meghan Blake, MD, a second-year radiology resident at BU Medical Center. "There's fear in trainees that somehow asking for special treatment will undermine their position at work and cause resentment on the part of fellow residents, male or female, who believe somehow they'll be asked to pick up the slack." She reported that although half the students in U.S. medical schools are women, only 23% of radiology residents are women. The team postulated that women considering radiology as a specialty were put off by concerns over potentially harmful levels of radiation should they become pregnant. The research team sent questionnaires to 187 radiology program directors and received 55 responses. Approximately half the respondents have a written policy for pregnant residents, although two-thirds report encountering concerns. Most programs instruct residents in methods to reduce radiation exposure and provide radiation counseling for pregnant residents as necessary. However, the study found that such information is informal and not made readily available for candidates interviewing for radiology residency positions. Some study responses pointed to a communication gap with female interviewees for residency positions. A majority (76%) of radiology residency program directors surveyed said they would

welcome a national standard policy regarding pregnancy issues.

Radiological Society of North America

Medical Errors and Length of Shift

Two studies published by a group of Boston researchers in the October 28 issue of the *New England Journal of Medicine* added fuel and quantifiable data to the debate over routine extended shift assignments in medical education. Lockley et al. (*N Engl J Med.* 2004;351:1829–1837) reported on the effect of reducing interns' weekly extended hour scheduling in intensive care units. The study included 20 first-year residents during a traditional 3-week rotation schedule that included extended work shifts and also during a 3-week intervention schedule that limited shifts to 16 or fewer consecutive hours. Subjects completed daily sleep logs that were validated with regular weekly episodes of continuous polysomnography and work logs that were validated by means of direct observation by study staff. The authors found that on the traditional schedule, 17 of the 20 interns worked more than 80 hours per week. On the intervention schedule, however, all interns worked less than 80 hours per week and, compared with the traditional schedule, averaged 19.5 fewer hours of work per week, slept an average of 5.8 hours more per week, slept more in the 24 hours preceding each work shift, and had less than half the rate of attentional failures during on-call nights. In a second study by the same group of researchers, Landrigan et al. (*N Engl J Med.* 2004;351:1838–1848) looked at the effects of sleep deprivation and intern work hours on serious medical errors in intensive care units. Again, the authors compared intern performance on a traditional extended work shift schedule and an intervention schedule that eliminated extended work shifts. They found that during a total of 2,203 patient days involving 634

admissions, interns made 35.9% more serious medical errors when working the traditional schedule than with the intervention schedule. The total rate of serious errors on the critical care units was 22.0% higher during the traditional schedule than during the intervention schedule. Interns made 20.8% more serious medication errors and 5.6 times as many serious diagnostic errors during the traditional schedule than during the intervention schedule.

New England Journal of Medicine

New National Cancer Incidence and Mortality Report

The most comprehensive federal report available on state-specific cancer rates for the first time includes information on incidence and death rates, as well as data for Hispanics and a new section on mesothelioma and Kaposi's

sarcoma. *U.S. Cancer Statistics: 2001 Incidence and Mortality* includes quality-assured incidence data from 43 states, 6 metropolitan areas, and the District of Columbia, covering 92% of the U.S. population—up from the coverage rate of 84% for the report issued last year. The report supplies essential state, population, racial, ethnic, and gender information for tailored cancer prevention and control programs nationwide.

This report marks the third time the Centers for Disease Control and Prevention and the National Institutes of Health National Cancer Institute, in collaboration with the North American Association of Central Cancer Registries, have combined data to produce federal cancer statistics.

The report also contains updated 1999 and 2000 cancer incidence rates and counts originally published in November 2002 and 2003, respectively. For the Web-based report

(<http://apps.nccd.cdc.gov/uscs/index.asp?Year=2001>), the available 1999 and 2000 cancer incidence data have been updated and enhanced to include 1999 and 2000 mortality data. Mortality statistics for both years cover 100% of the U.S. population. Additional updates will be incorporated in future Web-based report releases.

The latest report shows that prostate cancer is the leading cancer diagnosed overall in men in the United States and breast cancer is the most common form of cancer diagnosed in U.S. women. The leading cause of cancer deaths for both men and women is lung cancer. The report cites wide geographic differences in incidences of specific cancers.

In addition to the interactive Web version, the full report is available as a download at www.cdc.gov/cancer/ or www.seer.cancer.gov/statistics.

National Cancer Institute

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advancing molecular imaging

(with no risk of duplication) existing facilities specializing in the production of short half-life radionuclides used in diagnostic applications and research.

The cyclotron is expected to be operating in September of 2008 as a special scientific facility of the University of Nantes, supported by INSERM, CNRS, the Ecole des Mines de Nantes, the Nantes University Hospital, and the René Gauducheau Cancer Center. Mr F. Gauché, the

project manager, will coordinate development of the project under the supervision of a steering committee.

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