Bone Mineral Densitometry:

SNM/ACNP Opposes HCFA's Intention to Deny Medicare Coverage

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In a letter expressing strong opposition to The Health Care Financing Administration's (HCFA) stance on reimbursement for bone mineral densitometry, and noting the huge costs—financial and otherwise—that osteoporosis and other bone diseases exact, The Society of Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP) responded to HCFA's proposed rule regarding withdrawal of Medicare coverage for single photon absorptiometry and radiographic absorptiometry and continued non-coverage of dual photon absorptiometry (see *Newsline* Oct. 1988, p. 1620).

Malcolm R. Powell, MD, associate clinical professor of medicine at the University of California at San Francisco and a member of the SNM/ACNP Task Force on Reimbursement for Bone Mineral Density Measurements*, described the HCFA proposal as a "misdirected effort at cost-containment. . . .aimed at a test that has greater reproducibility than most tests that are run in medicine". Pointing out that the less-reproducible CT procedure is paid for, Dr. Powell said HCFA is being "inconsistent and irrational," by "paying for something that's inferior and denying something that's superior."

Ralph G. Robinson, MD, head of the division of nuclear medicine at the University of Kansas Medical Center, and chairman of the Task Force, told *Newsline*, "at no time has there been more unanimity of opinion among doctors in the osteoporosis field than now, that these procedures should be reimbursed."

The SNM/ACNP response signed by Presidents Barbara Y. Croft, PhD, and Myron Pollycove, MD, included the following key points:

- The SNM/ACNP does not endorse "mass screening" of asymptomatic patients for low bone mass and is concerned that the Office of Health Technology Assessment (OHTA), which evaluates medical devices and procedures for HCFA, "inappropriately focused on the issue of screening . . .the vast majority of medical experts agree that bone mineral density measurements are useful in diagnosing and monitoring treatment for specific, carefully defined medical indications."
- HCFA has largely based denial of coverage on OHTA reports that are over two years old. Evidence has since surfaced which supports the clinical efficacy of absorptiometry measurements.
- Bone density measurements provide clinically significant information, not obtainable through other available methods. "All current methods of determining bone mass have clinical utility. . .all of the current absorptiometry methods are far superior to simple x-rays in establishing the diagnosis of medically significant osteopenia."
- "The College and Society recognize that specific techniques or measurements of bone density at particular body sites may be more advantageous in certain age groups and in specific clinical situations than other body sites. . . .the best available information regarding osteopenia in specific body sites is derived from a measurement obtained at that body site."

The SNM/ACNP has identified specific medical indications for measurement of a patient's bone mass: for patients with premenopausal oophorectomy, spontaneous menopause, or estrogen deficiency conditions; for treatment-related osteopenia; when the diagnosis of osteopenia is suggested or established by other means, such as x-ray; during

**Ralph G. Robinson, MD, chairman; Stanley J. Goldsmith, MD; B. Leonard Holman, MD; Malcolm R. Powell, MD; B. Lawrence Riggs, MD; Heinz W. Wahner, MD.*

long-term immobilization; for endocrinopathies known to be associated with osteopenia; for post-gastrectomy and other malabsorption states leading to osteopenia; during long-term corticosteroid therapy; for chronic renal disease, particularly in childhood or adolescence; and to monitor treatment programs for osteoporosis.

"Limiting reimbursement to these specific indications," according to the Task Force, "should assure that the diagnostic technologies used for bone density measurements will be properly and selectively applied in clinical practice. These indications are well-supported by current medical literature and practice. . . ." Medicare coverage for these indications "represents a balance between the medical needs of our patients and HCFA's need to be fiscally sound."

The SNM/ACNP asked HCFA, which is reviewing the responses to the proposed rule, to consider their comments and those of a National Osteoporosis Foundation (NOF) Task Force on bone mass measurements, as well as meet with representatives of the nuclear medicine community before making its final decision.

Some members of the SNM Task Force view the HCFA proposal as a temporary setback, but see the long-term outlook more positively. Dr. Powell told *Newsline*, "I don't think [HCFA] will be able to introduce the restriction without reviewing all the response material. This will lead to a delay in implementation" of the restrictions.

Heinz W. Wahner, MD, professor of nuclear medicine at the Mayo Clinic and Foundation, and a member of the SNM/ACNP Task Force, said new drugs are being developed to treat osteoporosis and other bone diseases. Many of these drugs require some form of measurement. If these drugs, some of which have been approved in Europe, are approved in the US, added Dr. Wahner, absorptiometry measurements will be in even greater demand.

Dr. Robinson pointed out that the OHTA assessments were, in part, based on some previous opponents of absorptiometry techniques who have reversed their opinions and now support reimbursement for clinically-indicated bone mass measurements. He also noted the magnitude of responses to the HCFA proposal, from groups such as the American College of Radiology and the NOF in addition to the SNM/ACNP. "The combined efforts of all these groups has documented the usefulness of absorptiometry procedures. . . now we are waiting—hopefully for a positive response."

Sarah Tilyou

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HMPAO in cerebrovascular disease by Richard A. Holmes, MD, chief of nuclear medicine at the University of Missouri-Columbia and the Harry S. Truman Memorial Veteran's Hospital, and president-elect of SNM. Dr. Holmes, who held the only physician-sponsored IND for ^{99m}Tc HMPAO, pointed out the agent's potential in cerebrovascular imaging, particularly transient ischemic attacks. He said, "Ceretec is what we regard as a valuable agent . . . it is technetium-labeled. . . neutral, lipophilic and will cross into the brain. . . . it. . . will be extremely valuable to the clinical practice of medicine."

Dominick Conca, MD, of the FDA staff, presented the agency's positive review of the agent, noting, however, that they did identify some differences in interpretation between the investigators and the FDA reviewers. Questions of Committee members revealed that the study design included incomplete blinding of readers, and some thought a more realistic approach would be to provide reader training.

Gastric Emptying Petition

Describing the FDA's review of the gastric emptying petition, which involves approval of the oral administration of technetium sulpher colloid mixed with food to image and quantify gastric emptying, Joseph Zolman, MD, of the FDA staff, said the agency could not find evidence of efficacy in controlled or non-controlled studies. "We do not have enough of a body of data and evidence that at this stage a labeling change would provide for significant diagnostic advantage. . . . we would prefer to get by with a broader labeling change that is in favor of gastrointestinal motility." The Committee members expressed surprise at the FDA's inability to obtain evidence of efficacy for gastric emptying and concern that the lack of a labeling change may preclude reimbursement. There were further concerns that manufacturers would not be willing to invest in the controlled trials FDA requires for the labeling change. The possibility of changing the indication to gastrointestinal motility was considered, but in lieu of a general motion in that direction, the FDA agreed to review the petition again in light of the Committee's remarks.

A discussion of safety considerations and a proposed labeling revision related to the use of nonionic contrast media was deemed premature and deferred to a future meeting.

Sarah Tilyou