BLUES APPROVE INDICATIONS FOR PET

IN A MOVE LIKELY TO boost the clinical utilization of PET, the national Blue Cross and Blue Shield Association recommended in July that affiliated insurers provide limited coverage of positron emission tomography for patients with recurrent brain tumors or epilepsy.

Blue Cross and Blue Shield is the largest private insurer in the U.S. and its advisory panel recommendations are intended to help standardize coverage among affiliated insurers across the country. Blues in 16 states now provide some coverage for PET scans, according to the Institute for Clinical PET (ICP), a non-profit organization based in Washington, D.C. "PET is definitely going forward," says J. Michael McGehee, executive director of ICP.

Coverage far from Guaranteed

But individual Blue Cross and Blue Shield organizations are not bound by the Medical Advisory Panel's decisions. Affiliates such as Blue Shield of California have adopted coverage similar to the national recommendations while others, such as Iowa Blue Shield and Kansas Blue Shield, review PET claims case-by-case. Some companies flatly deny coverage for PET studies.

"Were not paying for PET," says Marvin B. Blitz, MD, medical director of Empire Blue Cross in New York. Nor does Pennsylvania Blue Shield pay for any applications of PET, according to Medical Director Joseph A. Ricci, MD. Neither company has immediate plans to reconsider PET coverage as a result of the national recommendation, the medical directors say.

Approved Indications

The Blues' national panel qualified its recommendations for PET and stopped short of recommending coverage of PET in clinical cardiology. PET scans are useful, the panel said, in the differentiation of recurrent brain tumors from treatment-related tissue necrosis, but should be eligible for coverage only when all conventional diagnostic techniques have been tried without success. The panel endorsed PET for localization of epileptogenic focus in patients with complex partial epileptic seizures when such patients have failed to respond to medical therapy and are candidates for surgical resection.

The advisory panel considers "investigational" all other applications of PET in the diagnosis and treatment of diseases of the central nervous system.

At least two affiliates, Blue Cross of California and Florida Blue Shield have gone beyond the national recommendation and adopted payment policies for PET studies of heart disease. The American Heart Association has tentatively endorsed the usefulness of PET in assessing myocardial viability – if the information could be expected to influence clinical management of the patient. The AHA found PET effective for myocardial perfusion imaging but not clearly superior to less expensive alternatives such as single-photon emission tomography for the detection or assessment of coronary artery disease.

Assessment Criteria

The Blues' national panel uses five basic criteria to assess new medical technology, including the stipulation that new devices have regulatory approval. The panel reviews the scientific literature to see that sufficient studies document the effectiveness of the technology. The panel also considers whether the device or procedure influences health outcome, and furthermore, whether the outcome is comparable or better than existing alternatives. Finally, positive outcomes should be widely obtainable and not just in specialized research hospitals.

ICP officials say the national policy decision will pave the way for broad coverage of clinical PET. Says John Mazziotta, MD, professor at UCLA School of Medicine and a past-president of the ICP: "The stage has now been set for Medicare reimbursement."

Medicare Coverage to Follow?

Over two years ago the Society of Nuclear Medicine and the American College of Nuclear Physicians petitioned the Health Care Financing Administration to extend Medicare reimbursement to selected PET studies. HCFA initially delayed its decision contingent on a review by the Office of Health Technology Assessment, which was asked to evaluate the clinical efficacy of PET in the localization of seizure focus, the differentiation of radiation necrosis from recurrent brain tumor, the assessment of myocardial viability, and the diagnosis and evaluation of coronary artery disease.

Since OHTA completed the review, however, HCFA has refused to release the results until the Food and Drug Administration approves the radiopharmaceuticals. The FDA has approved rubidium-82 chloride, which is used for assessing myocardial viability. But approval of fluorine-18 fluorodeoxyglucose (FDG), an important tracer used in brain, heart, and cancer PET studies, is mired in regulatory problems raised by cyclotron-produced tracers (see *Newsline,* September 1992, p. 24N).

An advisory panel to the FDA considering drug master file data from ICP recommended approval for FDG earlier this year, indicating some progress. Working with ICP, Methodist Hospital of Peoria, Illinois has submitted a new drug application (NDA) for FDG and according to Mr. McGehee, the NDA is "complete and in the final stages of evaluation." ■