FDA and HCFA announce new policy to pay for unapproved devices

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Restrictions will limit application of policy

Two federal agencies whose regulation of medical devices has made them the targets of industry critics have jointly developed a policy that promises to increase the access of Medicare patients to new technology while encouraging technological development.

The Health Care Financing Administration, which administers the Medicare program, and the Food and Drug Administration will soon begin a cooperative effort to provide Medicare coverage for the use of at least some uncleared and unapproved medical devices being used in clinical trials. While the policy appears to be a victory for the device industry, the agencies have applied substantial restrictions that will probably limit the policy's application.

The directive stipulates that coverage will extend only to Medicare recipients participating in clinical trials approved by the FDA as part of a company's efforts to win regulatory clearance or approval of the device. Further, not all medical devices being evaluated will be eligible for coverage. First of a kind or experimental devices are specifically excluded, because fundamental questions of safety and effectiveness have not been resolved, according to government officials. Yet, industry officials are hailing the move as an major step forward.

"It is important progress because last Dec. 28 (the government) issued a policy (stating) that it wouldn't cover anything (that was in clinical trials); now they have decided to cover at least 70% or more of these clinical trials," said Kristen Morris, director of government affairs for the Health Industry Manufacturers Association. "Considering that less than a year ago they were saying zero, it is definitely important progress."

In the past, Medicare has considered experimental any device requiring an investigational device exemption (IDE) as a prerequisite to clinical trials. As a result, use of these devices could not be reimbursed by Medicare. Under the new policy, such devices might be covered.

Digital mammography and ultrasound are two industry sectors that might benefit from the new policy. Earlier this year, the FDA stated that the manufacturers of full-view digital mammography equipment might have to generate clinical data to show the equivalence of this technology to conventional x-ray mammography devices. If such clinical trials are pursued, the door might be open for Medicare reimbursement of patients participating in the research.

The policy may also prove helpful for companies such as ATL of Bothell, WA, which has completed a study of the ability of ultrasound to assist in differentiating benign from malignant breast tumors (SCAN 5/18/94). The trial included about 1000 patients, according to a company spokesperson. ATL plans similar trials aimed at expanding the applications of its diagnostic ultrasound equipment. Company officials were not available for comment, however, on how the new FDA policy might affect the conduct of these trials.

Working out the details. The specifics of the new policy remain to be worked out. Even FDA and HCFA officials are uncertain as to which devices will be covered and under what circumstances. Although major government officials, including Department of Health and Human Services Secretary Donna Shalala, announced the policy on Sept. 14, the policy itself has not yet been released. It should be published shortly in the Federal Register, however, along with the criteria the FDA will use to decide which devices are eligible.

"We are cautious about FDA's involvement with HCFA policy," Morris said. "We are evaluating the extent (to which) FDA should be involved in defining what is essentially technology that can be covered by Medicare. We also feel that setting limitations on what is next generation versus breakthrough technology (that cannot be covered in clinical trials) may not necessarily be
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appropriate."
The policy will be applied mainly to next-generation technology, said Dr. Bruce Burlington, director of the FDA's Center for Devices and Radiological Health.
"The policy as envisioned is probably going to cover some off-label clinical investigations (as in the case of new ultrasound applications), but that is not the core of it," Burlington said. "The core is the evolutionary product."
Despite its limitations, the new policy is noteworthy on a number of fronts. The availability of Medicare coverage should help recruit subjects for clinical trials, thereby assisting in the development of new products, Burlington said.
Further, this coverage will reduce the economic burden placed on the investigators and device manufacturers conducting the trials. On a broader level, the policy is a milestone in the relationship between two agencies that have kept one another at arm's length in the past.
"Before (this policy was under development), there was not any formal relationship. We simply waited for FDA to certify a device for marketing and until that happened, we considered the device not to be safe or effective for Medicare purposes," said Chester Robinson, director of HCFA's Division of Durable Medical Equipment. "Given this new initiative, we started to have direct discussions with FDA to ask if it was possible to make some separation in these devices and, if we were to pay for some of them, which ones would be appropriate for us to pay for."
While the joint policy may launch a new era of cooperation between the two agencies, it does not signify any fundamental change in their missions, according to both Burlington and Robinson.
"You must not get the idea that FDA is going to be making reimbursement decisions," Burlington said. "We don't now and we are not looking to in the future. The FDA is only in the position of advising HCFA whether we regard a device as evolutionary or as substantially new. HCFA will have to translate that into reimbursement policy."
HCFA's Robinson echoed Burlington's views on the continuing separation of the responsibilities of each agency. Whereas the FDA is focused on determining whether a device is safe and effective, HCFA must decide whether the use of a product is reasonable and necessary.
Some critics have assailed the Medicare decision-making process as duplicating much of the process the FDA employs in making its decisions. They have suggested that a favorable FDA decision should translate directly into a positive Medicare reimbursement decision. But that is not how the process works, Robinson said.
"If it were that way, it would put the responsibility on FDA to determine what is covered under Medicare, and we certainly wouldn't want to go along with that," he said.

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