REIMBURSEMENT POLICIES

HCFA, INSURERS URGED TO PAY FOR TEST DRUGS

WASHINGTON, D.C.—Should insurers defray more of the expenses associated with caring for patients who are being treated with experimental drugs or with drugs explicitly approved only for other specific uses? Physicians, AIDS (acquired immunodeficiency syndrome) community activists, and some biotechnology companies argue that private insurers and the federal Health Care Financing Administration (HCFA) should reimburse more of these costs.

Recently, for instance, the prestigious National Committee to Review Current Procedures for Approval of New Drugs for Cancer and AIDS, part of the President's Cancer Panel, recommended that HCFA cover hospital, physician, and other medical-care costs for patients enrolled in cancer and AIDS trials. The committee sharply criticizes the current practices of HCFA and private insurers. "Peer-reviewed, scientifically sound trials provide state-of-the-art treatment for patients desperately needing such treatment but for whom ...[approved] drugs are ineffective," the committee says. "For such patients, scientifically meritorious investigational drug therapy is the best available therapy, and should be covered."

Moreover, the committee recommends that off-label usage of drugs—that is, uses not explicitly approved by the Food and Drug Administration (FDA, Bethesda, MD)—be reimbursed by HCFA. The appropriateness of such uses is to be based on the advice of an expert panel that would make recommendations supported by the medical literature and by current clinical practice.

Whether and how these recommendations will be implemented are unsettled questions. "Medicare now covers all drugs for labelled indications, but coverage of unlabelled indications is left to contractors," says Kathleen Buto, acting director at the HCFA Bureau of Policy Development, who spoke in October at the eighth annual meeting of the Industrial Biotechnology Association (Washington, DC). Moreover, the agency "historically doesn't cover" costs when patients are being treated with experimental drugs. Thus, Medicare does not cover promising drugs classified under the relatively new FDA treatment IND (investigational new drug) designation for fast-track clinical trials.

Typically, private insurers also do not cover such drugs, according to Susan Gleeson, executive director of the Technology Management Department of the Blue Cross and Blue Shield Association (Washington, DC). Blue Cross/Blue Shield, which insures more than 80 million individuals in 75 independent plans across the country, has a "contractual obligation *not* to pay for investigational treatments," she says. Although the companies are "rewriting contracts so as not to discourage research...the treatment IND is difficult to deal with," she says. Providing wider coverage for experimental AIDS drugs, for example, could mean extending similar coverage to other diseases and other types of experimental therapies. "This is a difficult issue for us," she says. "We're also trying to develop a consistent policy for unlabelled use of drugs."

Meanwhile, the promise of enlarged revenues is drawing some biotechnology companies into this arcane realm. For instance, when the FDA approved Amgen's (Thousand Oaks, CA) erythropoietin, HCFA approval for reimbursement under Medicare came almost simultaneously. This good timing was no accident; the company sent representatives to HCFA "a full year earlier to begin educating them," says Amgen CEO Gordon Binder.

HCFA approval came "very fast" and was based on very different considerations than those used by FDA, Binder notes. "From clinical trials, we could show improvements in workplace performance of patients [receiving the then-experimental drug] ...leading to increases in tax revenues and federal savings," he says. Although persuasive to federal officials, this approach makes some company representatives uneasy. Such "negotiated" reimbursement decisions, which may depend on revealing research and development cost information, are a "significant change from the past ...and could encourage less efficient R&D," says Patrick McKercher, director of drug policy analysis at the Upjohn Company (Kalamazoo, MI). Nonetheless, contends Binder, "Pharmaceutical companies must give much more consideration to reimbursement" sources of revenue. **—Jeffrey L. Fox**

FEDERAL REGULATION

NEW FDA BIOTECH OFFICE

WASHINGTON, D.C.—The U.S. Food and Drug Administration (FDA, Bethesda, MD) recently established a new Office of Biotechnology within the Office of the Commissioner, to be headed by Henry Miller, formerly a special assistant to FDA Commissioner Frank Young. Miller, who has been an aggressive proponent for liberalizing federal restrictions on biotechnology, says the purpose of the office is to coordinate FDA biotechnology activities within and outside the agency and to help implement the agency's 1989 "action plan" emphasizing biotechnology.

The office does not directly oversee agency regulatory activities. Instead, it will formulate and present "interagency policy recommendations to the commissioner and provide him with staff support for BSCC [the federal Biotechnology Science Coordinating Activity] activities," Miller says. He and his staff also will develop agency positions and provide background information for other federal and international biotechnology-related activities. Thus, for example, the office will represent FDA at meetings of other federal organizations, including the National Institutes of Health Recombinant DNA Advisory Committee, the U.S. Department of Agriculture Agricultural Biotechnology Research Advisory Committee, the Biotechnology Science Advisory Committee of the Environmental Protection Agency, and the National Council on Competitiveness. It is also "actively involved in the deliberations" of the European Organization for Economic Cooperation and Development, and will represent FDA at meetings with agencies of the United Nations and with Inter-American groups, such as the Pan American Health Organization.

The Office of Biotechnology also will "act as an ombudsman for environmental groups, companies, and biotechnology trade groups," Miller says. Because the office will help coordinate biotechnology activities among the regulatory "Centers" within FDA, it thus can open a window on those activities for outsiders. "We won't in any way tread on the day-to-day regulatory actions within the Centers and won't set their agendas," he says. "I promise the office will...keep the agency on the high road for bringing safe and effective products to market." **—JLF**