PHARMACEUTICAL REIMBURSEMENT A NATIONAL HEALTH POLICY ISSUE? IT MAY BE THE ONLY SOLUTION TO CONTINUING PAYMENT PROBLEMS

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Summary: *Solutions to the pharmaceutical payment issues raised in the first part of this two-part article cannot be left unresolved. Numerous options are presented in this article, some of which show little promise for inducing significant change, but others may be the types of approaches that eventually will prove effective in bringing about uniform, adequate payment for state-of-the-art cancer treatment.*

In the first part of this two-part article, the fictional Mrs. Green came up against some serious reimbursement barriers that essentially denied her access to the most promising treatment for her ovarian cancer. To set the stage for the following discussion about potential solutions to current and threatened chemotherapy payment delays and denials, let's paint a significantly different scenario for Mrs. Green.

Some elements remain the same. Mrs. Green is being treated with combination chemotherapy and one of the drugs is considered to be "investigational." While still under treatment, she makes plans to move from Florida to the state in which her daughter lives—Tennessee. Once again, her Florida physician does not foresee any problem in continuing her therapy in the new state. This time, however, not only does he refer her to a new oncologist, but continuing payment for her current regimen of treatment is guaranteed, regardless of what type of insurance Mrs. Green has or what state she lives in. In 1990, insurers, both private and governmental, adopted a uniform payment policy that covers the costs of all effective treatment, whether it's investigational or not. Efficacy requirements are updated and reviewed by the National Medical Practice Peer Review Committee, which takes into account clinical trial data, monthly information from the U.S. Pharmacopeia's *Drug Information* manual, quality of life factors, and available cost/benefit analyses.

Is this a plausible scenario after the rather grim payment picture that was painted in the first of these two articles? (See "Proposed Payment Changes Raise Quality, Innovation and Medical Judgment Issues" in the Winter 1988 issue of the *Journal of Cancer Program Management.*) Currently, there is considerable doubt about the continuing adequacy of payment for chemotherapy drugs, clinical trials, and new technological advancements in cancer therapy. However, all involved parties, from insurers to consumers, are looking at the impact that cost containment measures are beginning to have on quality of care. There are options to be explored. The key may be to involve all of the parties who have a stake in health care delivery.

EXPLORING THE OPTIONS

Decreasing drug costs. Cancer practitioners, insurers, and purchasers of care are all concerned about the increasingly high cost of new chemotherapy agents. What factors are involved in pharmaceutical manufacturers' pricing structures and can sufficient pressure be brought to bear to decrease those costs?

In 1987, more than $5.4 billion was spent on pharmaceutical research and development—an increase of 14.9 percent from 1986. What was the return on that investment for pharmaceutical firms? A total of 21 new drugs and six new biological products were approved by the FDA, and U.S. pharmaceutical sales totaled $27 billion.

Earlier this year, Burroughs-Wellcome Co., Research Triangle Park, NC, announced that it would lower the price of azidothymidine (AZT)—the only drug known to prolong the lives of AIDS patients—by 20 percent, because its own costs had dropped. However, according to Kathy Bartlett of Burroughs' public affairs department, AZT is not representative of most pricing situations. "AZT went from the laboratory to the market in less than three years," Bartlett explains. Because of that compressed timeframe, "there wasn't time to determine the most cost-efficient production process" before AZT was placed on the market. And, Bartlett says, production efficiencies were the reason Burroughs was able to decrease the cost of AZT nine months later. "That may not be the case with other drugs," she notes.

In its most recent report, the Joint Purchasing Corporation (JPC), New York City, which conducts an annual price forecast for medical supplies, predicted price increases of +0 to +5 percent for antineoplastic agents. The major factors that affect drug prices include research and development costs, production costs, lost interest on research and development investments, and, in the case of such drugs as AZT, the cost of financing continuing research. Another costly factor is the time required for FDA approval, which averaged 32.3 months for drugs approved in 1987. The Pharmaceutical Manufacturers Association (PMA) estimates that in 1985 (the most recent year for which data are available), 21 percent of R&D costs went to Phase I, II, and III clinical evaluations, and an additional 5 percent was spent on Phase IV trials.

Once a chemotherapy agent has been approved, a major determinant of price is the amount of competition present between manufacturers. Derwood Dunbar, executive director of the Council

of Shared Services, Inc., a service subsidiary of the Hospital Association of Pennsylvania and a wholesale purchaser of pharmaceuticals, explains that "because we bid drugs, we're able to keep prices low when there is competition"—that is, when generic therapies are available. But, he points out, the "push to get patients out of hospitals sooner requires, at times, more proactive treatment—in other words, more of the drugs prescribed are on patent."

Currently, the life of a patent for any product, not just pharmaceuticals, lasts 17 years. However, in 1984, Congress passed the Patent Term Restoration Act, which allows manufacturers to apply for patent life extensions of three to seven years. The criteria for the extensions are complex, but basically manufacturers can recapture the patent time consumed by the FDA's marketing approval process. The appropriateness of requests is determined by an internal FDA review board.

In the area of oncology, "most chemotherapy agents are still on patent," Dunbar says; a factor that he blames for significant price increases for commonly prescribed chemotherapy drugs that have been on the market for some time. For instance, the wholesale price for 50 milligrams of Adriamycin increased almost 40 percent between 1985 and 1988 and the price of Bleomycin increased 20 percent during the same timeframe.

Apparently, the only avenues for effecting substantial price decreases for antineoplastic agents are to shorten FDA approval times, decrease research and development costs, persuade government to pick up part of the tab for patient care costs in the research setting, or to reduce the life of patents to generate earlier competition with generic drugs—none of which hold much promise for significant change.

The treatment IND route. The Food and Drug Administration's attempt late last year to speed up the availability of investigational drugs for the desperately ill is certainly a step in the right direction, but issues such as who will pay for the drugs and associated medical care costs remain unresolved.

In addition, critics of the new Treatment IND regulations, such as Ronald Goodspeed, M.D., assistant vice-president and medical director, CIGNA Corp., believe that the FDA's intent is to "have insurers pay for clinical trials and investigational drugs, rather than manufacturers." He believes treatment IND is simply "one more push by the Reagan Administration toward the privatization of health care. That's a bitter pill for the insurance industry to swallow," he says, "particularly in the face of blue chip pharmaceutical firms."

Another criticism of the Treatment IND rule is that it doesn't go far enough. At the recent AMA/FDA meeting on Treatment IND (see page 24 for indepth conference coverage), participants such as William Garnett, professor, department of pharmaceuticals, Medical College of Virginia, Richmond, questioned why "the information required for Treatment IND did not constitute enough data to market the drug, especially in the case of patients with life-threatening diseases."

The FDA's only mandates are to determine what a drug contains, how safe it is, and that it is effective in at least one disease, Yarbro says. "FDA labeling was never meant to dictate indications."

That opinion was echoed by John Jennings, M.D., vice-president for science and technology, the Pharmaceutical Manufacturers Association, who contended that because "Treatment IND comes into effect at the end of Phase II or in Phase III trials, the FDA has data on which to judge a drug's uses. The time has come," he said, "to examine the overall criteria for drug approval." Finally, George Rathmann, Ph.D., president and CEO of AMGEN, a biotechnology company (after pointing out the barriers to implementation of treatment IND for small, innovative biotechnology firms, such as how to monitor trials and overcome approval delays resulting from fragmented data) stated that "what's needed is a second step by the FDA. When the FDA's Treatment IND deliberations are complete, declare the product as licensed for that indication. In that way," he contended, "we offer benefits to the desperately ill in time to help them."

A formulary approach to technology. There are burgeoning fears among such groups as the American Medical Association, that the outpatient drug prescription amendment to the catastrophic health care bill (H.R. 2470) will set the stage for a "cookbook" approach to determining the practice of medicine and, thus, the application of new technologies.

In early March, the AMA communicated its concerns to Rep. Dan Rostenkowski (D-IL), chairman of the House Ways & Means Committee, and proposed four amendments for adoption: 1) prohibit restrictions on a physician's ability to prescribe as long as it is medically accepted; 2) allow medically accepted prescribing for unlabeled use; 3) specify multiple current authoritative medical information for utilization review; and 4) establish an educational program to inform physicians about specific instances or patterns of inappropriate prescribing or dispensing.

If these proposed amendments are not included in the final bill, the AMA warns that the Secretary of HHS will be granted overwhelming authority in the determination of "standards for prescribing, dispensing, and utilization" of every covered outpatient prescription drug.

It is not only on the federal level that insurers are moving uncomfortably close to a formulary approach to drug payment. Traditionally, FDA approval has been the minimum payment requirement in most insurance contracts, and it has long been the policy advocated by the National Blue Cross and Blue Shield Association.

In addition, in September of last year, Blue Cross and Blue Shield of Minnesota—the state Medicare intermediary—issued a Medical Policy Update to providers that consisted of a 14-page list of experimental/investigative medical treatments that will not be reimbursed, as well as a one-page list of procedures that require preauthorization approval. Under the category "experimental drugs," the communication states that "any drug used for conditions for which FDA final marketing approval has not been granted and any new non-FDA approved drugs," will not be reimbursed.

Such a list, according to C. L. Murray, M.D., director of oncology, Methodist Hospital, Minneapolis, "goes a significant way in depressing new technologies." Insurers in the area are in an "uproar," he says. Blue Cross/Blue Shield alone lost $1 million on its HMO last year. Murray says there have also been recent "verbal" payment denials for patients treated with 5-FU and Leukovorin, although no "written" denials have yet been received.

But as John Yarbro, M.D., professor of medicine, University of Missouri, and chairman of ACCC's ad hoc committee on reimbursement stated at the Association's annual meeting, insurers are missing the point. "Congress charged the U.S. Pharmacopeia to review drug indications," not the FDA. The FDA's only mandates

are to determine what a drug contains, how safe it is, and that it is effective in at least one disease, Yarbro said. "FDA labeling was never meant to dictate indications." This is the message that must be told, he said.

The managed care option. Goodspeed of CIGNA Corp. points to the burgeoning number of managed care companies as a potential way to cut cancer treatment costs. These companies are "not a panacea," he is quick to say, but "they at least do some basic things like preadmission certification, particularly for elective admissions, and determining appropriate lengths-of-stay. In a broad sense," he says, "if cancer providers try to control costs in general, and can successfully make cuts in some areas, there is the potential for more dollars in other areas, such as chemotherapy reimbursement."

Managed care companies also provide very specific applications, such as high-cost case management programs where, because of a certain diagnosis or when a specific cost threshold is reached, the company will step in and manage the case, including presenting alternatives to inpatient care. This is the area in which Goodspeed believes that "groups like ACCC have the potential to play a large role: as a resource for outpatient chemotherapy protocols, the correctness of protocols, and the potential to identify quality outpatient chemotherapy centers." Managed care companies, he points out, want to be able to "identify providers in a geographic area that delivery cost-efficient, high-quality care."

Cathy Amkraut, director of health policy, the Washington (DC) Business Group on Health (WBGH), notes that "the first decade of cost management involved such strategies as preadmission review." But Amkraut says that large purchasers of care are now "delving into the delivery of care. There is nothing cost-efficient about poor quality," she notes. The problem is, "quality is much tougher to measure" than other aspects of care, such as resource utilization.

Patients will have to play a large role in the pressure brought upon insurers and purchasers of care to make interventive therapies available

Many of WBGH's members, "are using case management," Amkraut says. And it is in the area of case management that she believes guidelines or at least references about standard medical practice could be most effective, because case managers are looking at the patient's situation, available resources, and "how to best manage the delivery of care." In addition, reimbursement "rules and regulations are not as tight."

Determining treatment effectiveness. Recently, Paul Ginsberg, Ph.D., executive director, Physician Payment Review Commission (PhysPRC), said "One solution to increasing Medicare costs is likely to be the 'encouragement' of professional medical societies to become more active in educating physicians as to what is appropriate treatment."[1] That view is being expressed by a growing number of insurers and purchasers of care, especially in the area of cancer therapy. However, some major insurers, such as Blue Cross and Blue Shield, want information on what chemotherapy treatments do not work, but are unwilling to make any concessions regarding future coverage of promising new investigational drugs.

The Group Health Association of America (GHAA)—a DC-based HMO trade group—does not assess new technologies or "advise" its membership about what is considered standard medical practice. However, according to Joanne Boyce, in GHAA's medical directors division, it "tries to disseminate information as it becomes available about new technologies and treatments." For instance, it distributes appropriate information from the federal government, papers by professional societies, and all NIH consensus reports. It also has a database that it uses to track utilization for individual members.

Amkraut of the Washington Business Group on Health (WBGH), which represents primarily large, Fortune 500 companies, is "interested in the entire area of standard medical practice and, although WBGH has not been involved, to date, with disseminating information about standard medical practice to its membership, Amkraut says that "they wouldn't rule it out in the future." It would be "very useful if benefits managers, who are responsible for allocating resources over 100,000 employees or more, had some kind of clearinghouse they could call with questions about when a treatment is useful, what acuity of disease it should be used for, etc." Amkraut thinks that such "guidance for decisionmakers" is much needed, and that the WBGH would be interested in any group or organization that took on the role of disseminating information about effective medical treatment. "It is a need," she says, "that comes up not only in regard to cancer therapy, but in other contexts, such as pre-natal care." There has been a lot of arguing back and forth about "what constitutes standard medical practice" in that area, Amkraut notes, but there are still "no standards for procedures"—a fact which "does nothing to further reimbursement for those services," because there is "nothing definitive to base payment on."

Thomas W. Byrne, director of medical affairs, Blue Cross and Blue Shield Association of Massachusetts, also believes that some type of treatment review panel that disseminated information about the effectiveness of old and

QUALITY IS BUSINESS COALITIONS' #1 PRIORITY: SURVEY

Quality of care heads the list of business coalitions' priorities for the coming year, according to a survey conducted by the Office of Health Coalitions & Private Sector Initiatives of the American Hospital Association. The survey, which took place in late 1987, revealed that 80 of the 130 operating coalitions in the United States said that quality of care will top their agendas in 1988, followed by uncompensated care (70), malpractice (67), and mandated health benefits (66).

Some of the major activities that coalitions are involved in include: educational activities (121), designing employee health benefits (101), legislative analysis (90), and legislative advocacy (86).

With regard to the collection and evaluation of health care data—a high priority among responding coalitions—80 report that they have access to a database, 77 analyze data to identify utilization patterns, and 74 use the data for charge and cost evaluations. The majority of coalitions obtain their data from state data agencies, commissions, or consortiums, followed by employer claims records (42), Blues plans (37), and commercial insurance companies (30).

new drugs "would be very welcome." However, "not any one insurer or plan would adopt the recommendations at face value," he warns. "The key would be the ability of such a panel to document the rationale behind any decision," such as information about the studies the decisions are based on.

Nevertheless, Byrne says such information would "reduce the amount of research done by individual insurers and it could speed up changes in payment policies." Having access to such information "could at least get the ball rolling as far as the review process" is concerned. Currently, "we often receive inquiries from physicians about preauthorization requirements two days before a patient is scheduled to be admitted." Communication with those who are "on the front-line of treatment regimens would make payments decisions more readily available" by easing the time constraints that currently impede the review process. "In the absence of specific policy," he notes, "the answer is no."

Influencing insurers. "Third-party payers must see that providers' products are sold at a reasonable cost and consist of a reasonable level of quality," says David King, ACCC president. Goodspeed of Cigna says that "overall, insurers want to know what is viable, what is not, what's investigational and what isn't, and the appropriate uses for particular agents." When asked what it will take to improve chemotherapy payment, Goodspeed predicts that "it will be like swimming upstream at a time when corporations are demanding cost cuts and in the face of continuing cost increases. Initial attacks on health care costs, such as prospective pricing and pre-admission certification have had their little impact, but basically, I believe, they have simply shifted the cost curve to the right. What's out of control is the cost of care. The application of new technologies is driving health care costs off scale. We are constantly trying to decide what's appropriate and, even then, there is too much appropriate new technology to pay for it all. Chemotherapy falls under new technology in terms of its delivery. The only hope to increase reimbursement is the hope of cost shifting."

At a reimbursement panel discussion at the recent ACCC annual meeting, Susan Gleeson, executive director, technology management, Blue Cross and Blue Shield Association, noted that there is "no exception to [the Blues] FDA approval requirement" for drug reimbursement "among any of its 74 plans." However, she did note that the Association's technology review committee, which meets quarterly, will be reviewing the current policy for chemotherapy reimbursement at its next meeting as part of an overall review of the Association's uniform medical policy on drugs. She also noted that there is "renewed interest in investigational drugs as a result of the FDA's treatment IND rule.

However, Byrne from the Massachusetts Blues says that it is "not always feasible" for local plans "to stick with full FDA approval." The payment policies adopted by local plans "may be more liberal" than national guidelines, Byrne says, pointing out that the national plan doesn't have to pay claims. It's hard, he notes, for local plans to deny payment when physicians are submitting preadmission authorization requests and the drug treatments they are requesting are supported with citations from the medical literature or with copies of peer-reviewed articles on the treatment.

"In the vast majority of cases, we are still reliant on FDA approval," Byrne says, "but in the past 2 to 3 years, we have considered exceptions. The burden of proof," however, rests with physicians. "If we can be shown that an unlabeled indication has a track record, we will basically view it as an approved drug for that site."

In the end, regardless of variations between insurers as to what they will or will not cover, Goodspeed believes that "to influence third-party payers, you need to influence their purchasers. What the purchasers want, the insurers will provide," he says.

Involving purchasers and consumers. As large corporate purchasers of care, such as General Motors Corp., continue to experience unacceptably high health care tabs and insurance premium increases (GM spent $2.2 billion on health care in 1986 alone, and premium increases overall are running more than 20 percent so far this year), they are turning to managed care, utilization review programs, and other cost-containment strategies.

Gleeson of the National Blues points out that last year, Blue Cross and Blue Shield reported losses in excess of $1 billion, and insurance premium costs increased an average of 20 to 25 percent across the country. Insurers are "more accountable" to purchasers, she noted, and despite what may be a need for "creative" benefits for pertinent treatments, such as investigational drugs, she doesn't think that purchasers "will be receptive to premium increases" for such services.

It would be "very useful if benefits managers, who are responsible for allocating resources over 100,000 employees or more, had some kind of clearinghouse they could call with questions about when a treatment is useful, what acuity of disease it should be used for..."

One practical approach to influencing insurers through their purchasers was suggested by former ACCC President Paul Anderson, M.D., and raised by Yarbro of the University of Missouri, at the March ACCC annual meeting. Yarbro suggested that the ACCC "evaluate insurers' policies to determine whether or not they cover state-of-the-art cancer treatment" and to "tell the public what they're buying." Yarbro believes that such a strategy "may have an impact on the people who buy health insurance."

Both unions and consumer advocacy groups, such as the American Association of Retired Persons (AARP), as representatives of cancer patients and their families, are intensely concerned about quality of care and access issues. Another strategy that was raised by ACCC Executive Director Lee E. Mortenson and by Yarbro as a way to influence such groups was to "develop insurance contract language that will guarantee state-of-the-art care," and to go to such consumer advocacy groups as the AARP and unions such as the AFL-CIO and tell them if they want "quality care, this is the language that needs to be in your contract." Both of these proposals are now being examined by the ACCC board of trustees.

Involving cancer patients. Perhaps the most important consumer group of all that needs to be involved in reimbursement issues are cancer patients and their families.

Patients will have to play a large role in the pressure brought upon insurers and purchasers of care to make interventive therapies available. According to Glenna Crooks, Ph.D., a patient advocate with the Pagonis and Donnelly Group, studies show that patients have difficulty locating physicians to administer experimental drugs. The patients who need these therapies, she says, are "growing in number, they are vocal in their demands, sophisticated about experimental therapy, and knowledgeable about the drugs that are available in foreign countries, but not in the United States." Moreover, Crooks points out, "They are a willing group and want to participate in clinical trials. And, finally, she says, "contrary to the fears of researchers, this group describes itself in nonlitigious terms."

What are providers to do?

"The goal of ACCC is advocacy of patients in the arena of reimbursement, not necessarily as the advocate of institutions or individual members, although institutions and members will be served by that patient advocacy," says ACCC President David King. "As an advocate, we want to try to ensure that the highest possible level of quality of care is delivered in the most cost-effective manner. To that end, intermediaries, third-party payors, purchasers of care, including large businesses and both individuals and groups of consumers, potential patients, and providers of health care all need to be intensely concerned about these issues," King says. "We must guard against the danger that our ability to provide advanced state-of-the-art improved care to patients will be damaged by our cost-reduction efforts, either by holding the line or delaying the implementation of technology. We can't be overzealous in restrictions in the name of cost-effectiveness. The pendulum can swing too far. If the ACCC successfully fills the role of advocate for cancer patients and their families, then we will be [effectively] serving our members."

According to Mortenson, the Association is planning at least one major reimbursement conference that, like a previous meeting last fall, will bring new players to the discussion table, including purchasers, representative of large, self-insured businesses, groups such as the AARP and the AFL-CIO, as well as representatives of the insurance and pharmaceutical industries. Such parties must be educated about the issues and what is at stake if cancer providers are to have any real impact on future health care policy.

Can the issue be raised to the national health policy level? Even though King says that "from every aspect of the problem and every level of player [chemotherapy reimbursement] clearly is a legislative concern," he is "not convinced that health policy can be influenced."

Wittes of NCI points out that while the Health Care Financing Administration (HCFA) is constrained by law regarding what Medicare can and can't pay for—a situation that can be brought to the attention of Congress and eased through legislation—"the majority of patients are on private insurance." He has been "in touch with various insurance companies and, although the responses vary," he has not detected any "real interest in lifting research exclusions from the way policy contracts are written." And he doesn't believe that there will be any "real move to change policies from within" either sector. "The pressure must come from outside," he says. "The insurance industry is unlikely to do anything without more of a public outcry," and currently, there is "no pressure on insurers with the exception of those who are involved in clinical research and the cancer patients and families who are being denied coverage for clinical trials." However, the decentralization of the insurance industry (there are 75 to 80 completely independent plans within Blue Cross/Blue Shield alone), makes it "a knotty issue to solve."

Government, as both a major insurer and purchaser of care through the Medicare and Medicaid programs, as well as a payment policy decisionmaker whose lead other insurers often follow, must be influenced. It is important for providers to be able to make persuasive cases before Congressional leaders.

Rep. Fortney "Pete" Stark (D-CA), chairman of the Ways & Means Health Subcommittee, recently said that a "more reasoned health policy debate" could be brought about if "we can begin using real empirical data. I can deal with balance sheets and operating statements quite well," he says. "It's tough to "make numbers lie," and "comprehensive data will help."

When asked how Medicare policy *should* be formulated, Stark replied: "As a wholesale purchaser of Medicare services, our committee could go to communities around the country and take the lowest price from any hospital in town. We could go out and buy procedures in the market. This is what a lot of supply-side economists think we should do—let the marketplace decide."[2]

In another interview, Rep. Henry Waxman (D-CA), chairman of the House Energy and Commerce health subcommittee, acknowledged that "deficits are driving health care policy in a way that's doing a great disservice to Medicare patients and to the nation's health care system. The health care community must bring that message to Washington." He went on to speak of the "frustration" he feels because "the politics of the deficit seem to be the dominant politics of the moment and are being viewed to the exclusion of the broader picture of trying to deal with the deficit in a way that will not do more harm to health care." He cited such "deficit politics" as an "unrealistic way for government to respond to the needs of patients. Congress," he said, "has lost the balance between cost savings and meeting [people's] health care needs."[3]

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SUMMARY

Reimbursement issues will not be easily resolved, but providers and organizations, such as the ACCC, are looking hard for solutions and ways to bring the issues to the public's attention. A recent brief article in *USA Today*, which simply stated that many people are not taking advantage of current clinical trials, provoked an overwhelming level of interest on the part of consumers. The interest in state-of-the-art cancer treatment is there; it's up to health care providers to influence reimbursement decisionmakers and to educate consumers about the threats that such care faces, both now and in the near future. ■

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[1] Robinson, M. Ginsberg: The Physician Payment Debate Begins. *Hospitals*. 62:80, 1988.

[2] Finn, J. Stark: How to Win Friends and Influence People. *Hospitals*. 62:83, 1988.

[3] Finn, J. Waxman Cites the Government's Policy Failures. *Hospitals*. 62:64, Feb. 5, 1988.