

UC Berkeley

UC Berkeley Previously Published Works

Title

Insurers' Strategies For Managing The Use And Cost Of Biopharmaceuticals

Permalink

<https://escholarship.org/uc/item/6sh5t6c3>

Journal

Health Affairs, 25(5)

ISSN

0278-2715 1544-5208

Author

Robinson, James C

Publication Date

2006-09-01

DOI

10.1377/hlthaff.25.5.1205

Peer reviewed

Insurers' Strategies For Managing The Use And Cost Of Biopharmaceuticals

Because no U.S. central government is making decisions about high-cost biologics, insurers are leading the way in forming social policy.

by **James C. Robinson**

ABSTRACT: This paper examines strategies under development by health insurers to manage biopharmaceuticals, as their use spreads beyond rare diseases and academic subspecialists to common conditions and community-based practices. Emphasis is placed on medical management (formulary placement and prior authorization), network design (physician contracting and drug distribution), and benefit design (coinsurance and annual payment limits). Contemporary initiatives are modest in ambition but potentially lay the foundation for a framework that balances access to innovation with affordability in this dynamic industry. [*Health Affairs* 25, no. 5 (2006): 1205–1217; 10.1377/hlthaff.25.5.1205]

WHEN USED IN RIGOROUSLY CONTROLLED research contexts, biopharmaceuticals can remediate some of society's most intractable illnesses but, once diffused into the broader clinical community, are subject to the characteristic challenges of contemporary medicine: overuse, underuse, and misuse. Biologics (medical preparations derived from living organisms, not chemical compounds) are evaluated by the Food and Drug Administration (FDA) for narrow therapeutic indications, only rarely with comparison to current standards of care and never with regard to cost-effectiveness. They then legally can be prescribed by physicians for conditions, comorbidities, and severity levels different from those studied. Biologics are bought and sold in an economic market where the customary fee-for-service (FFS) incentives to do more are multiplied by physicians' ability to purchase and resell the drugs at a profitable markup. The high price of biopharmaceuticals makes them affordable only to people with insurance, but the uneven pattern of coverage and coinsurance renders many insured patients indifferent to cost, while others agonize over the risk of financial destitution.

Spending on biopharmaceuticals accounts for only 1 percent of health insurers' current costs but is rising at a double-digit rate that threatens only to accelerate, as hundreds of new products are poised to emerge from clinical trials and be

Jamie Robinson (james.robinson@berkeley.edu) is the Kaiser Permanente Distinguished Professor of Health Economics at the University of California, Berkeley, School of Public Health.

launched at prices ten to one hundred times higher than those of the conventional drugs they replace.¹ The strategies being formulated by insurance companies reflect the scientific uncertainty, administrative complexities, financial risks, and regulatory conflicts endemic to emerging technologies and the health care system. Health plans bring to the task their core processes, including medical management (pharmacy formulary coverage and prior authorization), network design (physician contracting and drug distribution), and benefit design (consumer cost sharing and payment limits).² This paper examines contemporary medical management, network, and benefit design initiatives, based on discussions with numerous insurers and specific examples from health plans in two very different geographic markets, identifying opportunities for and challenges to any effort to prioritize who gets what from the cornucopia of sometimes miraculous but sometimes misused biopharmaceuticals.³

Medical Management Strategy

Biopharmaceuticals typically are evaluated by the FDA for narrow diagnostic indications, patient populations (for example, by age and disease severity), and therapeutic regimens (for example, use simultaneous with or subsequent to other therapies). Physicians, however, may prescribe any medication for any patient, including for “off-label” uses not evaluated or approved by the FDA. Health plans maintain pharmacy and therapeutics (P&T) committees, comprising mostly network (nonemployee) physicians and pharmacists, which review the clinical evidence used by the FDA plus other relevant materials (such as evidence on efficacy compared with other therapies). Much of medical management policy for biologics can be interpreted as insurers’ efforts to enforce the FDA label and limit the use of the often high-risk biologics to indications for which they have been adequately studied for safety and efficacy. Coverage policy among health plans is not designed to evaluate the therapeutic value of particular treatments relative to their economic cost. The country is ambivalent concerning the role for cost in insurance coverage policy, and Medicare is explicitly prohibited from using cost-effectiveness analysis.⁴ Public opinion would be even less tolerant of a private insurer that attempted to deny coverage of a biologic that created any health benefit, no matter how small, just because of the financial cost, no matter how large.

While health plans cover FDA-approved indications for most biologics that lack therapeutically equivalent alternatives, exclusions and other coverage limits do appear in treatment categories containing multiple products. An analysis of 1,360 product formularies offered by private insurers under Medicare Part D in ten large states, accounting for half of all beneficiaries nationwide, found extensive exclusions in several disease and condition categories, including rheumatoid arthritis (RA), end-stage renal disease, multiple sclerosis (MS), insomnia, and psoriasis (but not HIV and most cancers).⁵

The main emphasis of medical management policy is not coverage per se but

coverage under specified conditions, including step therapy and prior authorization. Step therapy requires, as a condition for reimbursement, that the patient has been prescribed accepted therapies and failed to respond adequately, before moving to biologics. Prior authorization requires that the prescribing physician submit diagnostic and other information, typically as defined by the FDA labeling, for reimbursement to be provided.

Another component of medical management for biologics, beyond FDA labeling and evidence review, formulary placement, and prior authorization, is integrating these products into a complete care plan, sometimes by referring patients to complex case management programs. Most insurers manage or contract for disease management programs covering patients who suffer from chronic conditions such as diabetes and asthma, seeking to identify, stratify, and offer services according to level of disease severity.⁶ Biologics do not play a large role in these programs now because the prevalence is low and the severity of the diseases is so high that the patients are more suited for high-touch complex case management programs. Patients need help in obtaining and administering their biologics, monitoring potentially severe side effects, coordinating with relevant clinicians and facilities (such as specialists, home infusion agencies, and hospital outpatient clinics), and identifying financial subsidies to offset the often large coinsurance expenses.

■ **Blue Shield of California.** Blue Shield of California (BSC) covers 3.3 million enrollees statewide and has long been active in assessing and managing new clinical technologies. Its P&T committee reviews comparative efficacy studies and, while approving biologics for all FDA-approved indications, might require the use of other proven therapies in a stepwise fashion. For conditions for which biologics are proven to outperform alternatives, the main emphasis of the prior authorization program is ensuring that the patient has the correct diagnosis and is under care by a physician in the appropriate specialty. The prior authorization process can require more extensive documenting materials, periodic reevaluation of the patient's condition and response to treatment, and denial of coverage if a biologic is prescribed for specified off-label diagnoses for which there is no supportive peer-reviewed literature. Prior authorization is most likely to be effective at the time of product launch, when the pattern of use has not been established, and then tends to decline in efficacy as use patterns become stabilized.

Prior authorization has been used extensively at BSC to review requests for biologic treatment for autoimmune diseases such as rheumatoid arthritis and psoriasis, where there exist a plethora of severity levels, treatment options, methods of administration, and financial incentives. Standard treatment for RA has moved beyond symptom reduction (for example, anti-inflammatories) to disease-modifying nonbiologics such as methotrexate, and then to an expanding list of high-cost injectible and infusible biologics. Given the often severe nature of this condition, prior authorization requires only that the patient's condition be diagnosed by a rheumatologist (the prescribing physician need not be a rheumatologist) and

“Patient involvement in therapy is important for diseases such as MS, where biotech products do not merely alleviate symptoms.”

.....

that the patient have tried and exhibited an inadequate response to methotrexate or another disease-modifying nonbiologic drug. For psoriasis, where ease of use and cosmetic factors can lead to prescription for mild symptoms, prior authorization requirements are more extensive.⁷

A different set of concerns drive the prior authorization for Xolair, an office-injected biologic for moderate-to-severe allergic asthma. Asthma is one of the most prevalent chronic conditions in the United States, and the addition of \$15,000–\$40,000 Xolair treatment even for the 10 percent of patients with severe allergic conditions would be an economic event of the first order. Although off-label “indication creep” to rhinitis and peanut allergies is already occurring, the greater concern is the simultaneous underuse of conventional therapies known to be effective and overuse of Xolair for patients with mild asthma or for preventive purposes.⁸ After the product was launched, BSC experienced a surge of prescriptions for patients who had not attempted standard therapies or who had conditions for which Xolair does not have FDA approval, resulting in a denial rate as high as 50 percent. Subsequent requests for Xolair are much more in line with FDA-approved uses, and authorization denials have declined and now are rare.

■ **Independence Blue Cross.** Independence Blue Cross (IBC) covers 3.5 million enrollees in Philadelphia and surrounding communities. It maintains conventional disease management programs for chronic conditions but contracts with a specialty care management firm to offer services to enrollees with any of fifteen complex conditions such as MS, Gaucher disease, RA, and hemophilia. These programs help patients understand their disease, symptom improvement, comorbidities, complications, the range of alternative treatments and methods of administration, and the range of professional and community-based resources.

Patient education and involvement in therapy is particularly important for diseases such as MS, where biotechnology products retard disease progression and do not merely alleviate symptoms, but where complications and adverse side effects can be serious. All IBC patients with MS are eligible for professional referral or self-referral to case management, which seeks to educate the patient, improve self-monitoring and self-care, and facilitate access to neurologists and other professional services. Understanding the role of beta-interferon biologics is only one of many aspects of the case management program, but an important one given the importance of quick response to flare-ups in symptoms, which, if untreated, may lead to progressive loss of neurological function. Behavioral factors such as depression are a frequent obstacle to effective treatment, as is the confusing plethora of providers, products, and treatment locations (for example, durable medical equipment, home health care, and emergency room services).

Network Strategy

Once approved by the FDA and the insurer's P&T committee, biologics diffuse into clinical practice through a complex and conflicted supply chain of drug wholesalers, specialty pharmacies, retail chains, academic medical centers, and physician practices.⁹ Distributors vary in scale, sophistication, and financial alignment. Some make major investments in facilities and networks to acquire, store, ship, and service the biologically fragile substances, while others, including many physician practices, operate on a mom-and-pop scale and rely on local connections and the intertwined roles of drug prescriber and vendor. Physician practices vary in patient mix, capabilities to manage infusion and injection, organizational relations with hospitals, and bargaining leverage with insurers.

Health plans are pursuing three intertwined network and distribution strategies. In designing physician networks, they seek to balance the virtues of channeling patients to large, sophisticated practices with the contrary virtues of broad provider choice and competition. In designing distribution networks, they seek to consolidate purchasing and servicing through a limited number of contracted or owned specialty pharmacy providers. In designing payment methods, health plans seek to move physicians off cost-plus "buy and bill" reimbursement and, in capitated contexts, develop risk-sharing arrangements that maintain incentives for physicians to concern themselves with the cost of care.

■ **Physician network.** The network of physicians who administer biologics has been limited until recently to a narrow range of self-selected specialists and subspecialists, but it now is broadening as more products enter the market for common chronic conditions. The cost and complexity of these products, and the substantial variability in clinical practice patterns, motivate health plans to consider directing patients to large specialty practices with substantial infrastructure and experience. However, the continuing public backlash against managed care and its network restrictions work against such channeling, and the more recent trend toward provider consolidation and pricing leverage dampen insurers' enthusiasm.¹⁰

Physician network design is a modest component of overall insurer strategy, and is limited to several basic tactics. First, the dominant insurance products all impose some network structure, as enrollees receive only limited coverage if they use the services of physicians who refuse to accept the health plan's contractual terms. Second, health plans can mandate consultation with or treatment by physicians in a particular specialty, to the exclusion of primary care and nonrelated specialties. Third, prior authorization mechanisms generate data on prescription use patterns that potentially lay the basis for differential treatment of physicians within the approved specialty (for example, favored exemption from authorization requirements for physicians with conservative use patterns).

Needless to say, physicians have their own ideas concerning appropriate network relations, and specialists in some markets are forming single-specialty groups or aligning with hospital systems, subsequently pursuing an all-or-none

contracting strategy that effectively dictates the insurer's specialty network. In Philadelphia, the physician community remains highly fragmented without significant multispecialty or even single-specialty groups, but is consolidating around hospitals and academic medical centers. IBC is concerned lest changes in payment and other network incentives drive the administration of biologics from community-based practices into hospital outpatient departments, where costs and provider pricing leverage are much greater. Many health plans pay hospitals a percentage of billed charges, which typically are highly inflated relative to underlying costs, thereby making the price of biologics much more expensive in a hospital than in a physician practice setting.

In California, many physicians belong to multispecialty medical groups and independent practice associations (IPAs), some of which are further affiliated with hospital systems.¹¹ These physician organizations tend to be dominated by primary care rather than specialty physicians, however, and often subcontract for specialized services with independent specialty practices (some of which are highly consolidated). To the extent that the capitation payment to the medical group covers the cost of biologics, the group is motivated to narrow its specialist network and manage the cost of these products. To the extent that biologics are carved out of capitation and reimbursed directly by Blue Shield on a cost-plus basis, however, the medical groups do not invest in biologics management programs.

■ **Drug acquisition and distribution.** Biologics have been administered largely in the physician office or specialty clinic as an adjunct of the professional practice of medicine and hence have been purchased by and reimbursed to the physician rather than distributed through retail pharmacies. Physicians purchase products from wholesalers or directly from manufacturers, administer them to patients, and then bill insurers for reimbursement, traditionally at prices much higher than those they paid. "Buy and bill" distribution undermines any insurer effort to extract volume price discounts from biotechnology manufacturers, who thereby sell into a fragmented market. If accompanied by large price mark-ups, "buy and bill" gives financial incentives to physicians to prefer high-price, office-administered biologics over products that can be obtained through independent pharmacies.

Insurers seek to shift the acquisition and distribution of self-administered biologics to specialty pharmacy firms, which have developed manufacturer contract discounts, warehouse facilities, home and office distribution networks, and patient education and support processes.¹² The specialty pharmacies consolidate purchasing volume across health plans and, in principle, could obtain price discounts from manufacturers. Manufacturers are holding to nondiscounted list prices, however, given the monopoly position of most therapies, and are developing their own networks of favored distributors. Health plans have unpleasant memories of divided loyalties and opaque pricing policies at pharmacy benefit management (PBM) firms, most of which now own specialty pharmacy subsidiaries, and they seek to ensure that their interests are truly aligned. Some are narrow-

“The incentives facing physicians in small practices and FFS reimbursement strongly promote prescribing of high-cost biologics.”

ing the number of specialty pharmacies (which often focused on one therapeutic category but now are diversifying) or, in a few cases, buying or building their own specialty pharmacy subsidiary. To the extent that multiple therapeutically equivalent biologics are emerging for the same conditions, insurers seek volume rebates from biotechnology manufacturers beyond any front-end discounts obtained by the specialty pharmacy distributor.

■ **Payment methods.** The financial incentives facing physicians in the cottage industry of small practices and FFS reimbursement strongly promote prescribing of high-cost biologics. Once physicians have invested in the office infrastructure to purchase, store, and administer biologics, they require high patient volume to cover overhead costs. The traditional FFS payments for professional services such as diagnosis, prescribing, and administration are compounded by the substantial profit margins to be obtained from the purchasing (from manufacturers and distributors) and selling (to insurers) of the drugs themselves. Markups from this “buy and bill” distribution mechanism can dwarf the professional fees paid by insurers for the actual administration of the drugs. For example, a 2002 survey reported that 70 percent of revenues for oncology practices come from drug markups rather than professional fees.¹³ Some physicians have additional financial relationships conducive to embracing biologics, including paid membership on advisory committees, speaking honoraria, expenses-paid medical education programs, and fees for participating in clinical trials.

In a FFS environment such as Philadelphia, the physician payment strategy of greatest import to insurers is the attenuation of the incentive to prescribe costly biologics for off-label purposes or where less costly therapies are effective. Medicare has led the way in reducing the payments it will make for drugs and increasing the fee it pays for administration, thereby permitting physicians to maintain “buy and bill” practices but eliminating most of the price markup. Private insurers such as IBC have less ability to impose unilateral payment changes and face skepticism from physicians that any change in payment method hides a simultaneous reduction in payment levels. It often is impractical to replace “buy and bill” for biologics administered in the physician’s office. For biologics self-administered by the patient, however, IBC would prefer physicians to relinquish their distribution role to specialty pharmacies altogether. Mandates for use of these specialty pharmacies is possible only where physicians are not yet attached to “buy and bill” reimbursement, and so IBC focuses these efforts on new biologics and on non-oncology specialties.

In markets where physician groups are paid on a prospective capitation basis, such as California, payment strategy revolves around the position of biologics in

the division of financial responsibility between insurer and provider. Traditionally office-administered drugs were considered incident to the practice of medicine and were included by BSC in medical group capitation payments, whereas oral drugs were paid directly by the insurer to the pharmacy. The rapid rise in use and cost of biologics threatened the financial viability of prepaid group practices, given the administrative lag in adjusting contracted payment rates. Many physician groups have “carved out” infused and injected biologics, renouncing capitation for the products and either demanding cost-plus (“buy and bill”) reimbursement or shifting distribution to specialty pharmacy firms. BSC offers three contractual options to capitated medical groups and IPAs: Biologics can be (1) included in capitation (which then is actuarially adjusted to account for their expected use and cost), (2) excluded altogether (with commensurate reduction in capitation payment), or (3) reimbursed through a hybrid arrangement whereby the physician organization bears partial financial responsibility. Blue Shield is seeking to slow the erosion of capitation, given its cost-control incentives in an otherwise inflationary context, without shifting unmanageable financial risks to the providers.

Benefit Design

In the wake of the backlash against managed care, insurers have focused their cost-control initiatives on consumers rather than providers, substituting deductibles and coinsurance for capitation and utilization review. Much of the impetus comes from employers, which seek to reduce the growth in their premium payments by increasing employees’ responsibility for payment at the time of receiving care. The poster child for this new emphasis has been outpatient pharmaceuticals, where tiered formularies with variable copayment levels have induced a major shift in demand toward generic and discounted brand-name drugs.¹⁴ Insurers are attempting to replicate this strategy for biopharmaceuticals, but efforts are complicated by the economic cost and complex modes of administration of these medications. Standard copayment tiers of \$10, \$20, and \$40, for example, are of little relevance for guiding consumer choice among products that cost more than \$10,000 per year, have no generic substitutes, and are difficult even for physicians to compare with alternative treatment regimens in the absence of data on comparative efficacy.

The most basic and yet most frustrating obstacle to the rethinking of benefit design is the historical division between medical benefits, which cover physician services and the products administered by physicians in their offices, and pharmacy benefits, which cover oral drugs obtained by the patient from a pharmacy. Office-administered biologics historically have been covered under the medical benefit rather than the tiered formulary structure dominant with pharmacy benefits. Biologics taken orally or self-injected by the patient can be covered by either the medical or the pharmacy benefit, a matter of more than administrative concern

in the not-infrequent context where the employer contracts with one insurer for the medical benefit and a different firm for the pharmacy benefit (or does not cover pharmacy benefits at all). Benefit designs for both medical and pharmacy services vary greatly between preferred provider organization (PPO) products, which emphasize deductibles and high (less generous) annual payment limits, and health maintenance organization (HMO) products, which impose dollar copayments and lower (more generous) limits on total patient payments. Designs vary among customer segments, with rich benefits common among large corporations and public agencies while thin benefits with high cost sharing are dominant for products sold to individuals and small firms.¹⁵

The insurers' approach to benefit redesign is to move as many biopharmaceuticals as possible from the medical to the pharmacy benefit and to restructure the medical benefit to mimic the pharmacy benefit for products that remain. Primary candidates for movement to the pharmacy benefit include oral biologics, self-injected substances, and biologics that although administered in the physician's office can be obtained by the patient through a specialty pharmacy vendor without interrupting the workflow in the office. The pharmacy benefit often is restructured to accommodate these costly substances, with the addition of a fourth tier in which the patient is subject to greatly increased financial responsibility. Salient features in the emerging pharmacy benefit designs include the substitution of percentage coinsurance (typically 20–40 percent) for dollar copayments in the fourth tier, pharmacy-specific deductibles that must be met independent of the medical benefit deductible, and the raising of annual limits on maximum consumer payment. Some insurers seek to impose similar pharmacy benefit designs across all products, whereas others continue to shelter HMO enrollees while permitting enrollees in PPO and high-deductible "consumer-driven" products to bear sizable financial responsibility.

Medical benefits, as distinct from their pharmacy counterparts, group biologics with physician and hospital services in defining coverage and cost-sharing provisions. The patient's exposure to financial risk can be very high, as the full weight of the deductible and coinsurance provisions fall on biologics. It also can be very low, because deductibles and annual payment limits may be met by physician services and hospital services, thereby exempting the patient from any further contribution for biologics. Coding ambiguities and information technology deficiencies in the physician office can prevent patient and insurer alike from distinguishing how much of the billed charge is due to the cost of the drug itself versus other professional fees. There is no simple way for tiered formularies to influence behavior when the physician, rather than the patient, purchases the product and when the physician's "buy and bill" reimbursement formula creates financial incentives to choose costly medications.

■ **Blue Shield of California.** BSC has moved self-injected biologics from the medical to the pharmacy benefit and imposed cost-sharing provisions that vary by

“P&T committees cannot serve as society’s fulcrum for comparing and balancing the cost and quality of novel therapeutics.”

.....

product and customer segment. The pharmacy benefit in the PPO has a fourth tier for biologics, with 30 percent coinsurance that does not accrue toward the deductible (and hence must be paid in addition to paying for physician and hospital services under the deductible). In the individual and small-group market, where concerns over adverse selection are greatest, there generally is no out-of-pocket payment limit, which implies that the patient’s 30 percent responsibility extends for the full cost of the biologic. Small firms can elect to offer a payment limit of \$150 per prescription per month, in exchange for paying a higher premium, and payment limits are standard in the large-group market. The pharmacy benefit in the HMO product for biopharmaceuticals is 20 percent coinsurance up to a maximum of \$100 per prescription per month; one-third of clients choose to substitute dollar copayments for percentage coinsurance in the HMO.

BSC enrollees receiving office-injected or -infused biopharmaceuticals through the PPO are responsible for the physician office visit copayment, 100 percent of product cost up to a \$250 drug deductible, and then 20 percent of product cost beyond \$250. The office visit copayment and product coinsurance accrue toward the medical deductible and thence toward the annual out-of-pocket payment limit. Medical benefits under the HMO are much richer: The enrollee is responsible only for the office visit copayment and not for any portion of the cost of the drug itself. Blue Shield is concerned over the disparity in coverage between the HMO and PPO pharmacy and medical benefits and is considering moving toward deductibles and coinsurance (from copayments and generous coverage) in the HMO to slow the migration of high-utilizing consumers into that product.

■ **Independence Blue Cross.** IBC is undergoing a fundamental transformation of its benefit portfolio to permit customers to select among high, medium, and low coverage levels for each component of care separately, with trade-offs between coverage completeness and premium price at each level. Under the new Flex benefit design, employers select among three basic product structures (HMO, PPO, or point-of-service), three copayment levels for the major components of ambulatory care (for example, physician visits, physical therapy, rehabilitation therapy, diagnostic tests, and radiology), four copayment levels for facility services (for example, ambulatory surgery, hospital per day charges, nursing home, emergency room, and durable medical equipment), and two deductible and coinsurance choices for non-network providers. For example, a firm could choose low copayments for physician visits and diagnostic tests, moderate copayments for ambulatory surgery and hospital care, and high coinsurance for out-of-network services.

Within the Flex benefit structure, IBC customers can select among three levels (\$50, \$75, and \$100) of copayment (not coinsurance) for self-injected and office-

injected biopharmaceuticals if these are obtained through network physicians and specialty pharmacies. If enrollees use the services of specialists outside the IBC contractual network, however, they are responsible for percentage coinsurance (choosing between 50 percent and 70 percent) up to the insurer's allowed amount per drug, and then 100 percent of charges above that amount. Out-of-network coinsurance payments are subject to annual out-of-pocket maximums, with a range between \$3,000 and \$10,000 for individuals and between \$9,000 and \$30,000 for families. The benefit options for biologics and other pharmaceuticals apply to all three basic product structures, although there is no out-of-network coverage for the HMO product.

The Limits Of Insurers' Strategies

Contemporary strategies by health insurance plans potentially improve the manner by which biopharmaceutical products are prescribed, purchased, and used. Formulary placement and prior authorization limit the use of high-cost and high-risk biologics beyond the bounds of safety and efficacy, as evaluated by the FDA. Physician network contracting and specialty pharmacy distribution moderate the incentives for doctors to prescribe the most costly rather than most cost-effective medication. Consumer coinsurance provisions motivate patients to concern themselves with the comparative expense of alternative treatments and might foster a grassroots constituency for the use of cost-effectiveness analysis in health care. More generally, health plans' strategies provide some counterweight to the otherwise dominant ethos that any doctor can prescribe any medication for any patient without regard to the economic implications.

The limited ambition of contemporary insurers' initiatives is immediately evident, however. P&T committees and their prior authorization programs possess only modest social legitimacy to decide which patients should receive which drug in a context of scientific uncertainty. They cannot serve as society's fulcrum for comparing and balancing the cost and quality of novel therapeutics. Insurers' network strategies are hobbled by being inserted into the often-conflicted contractual relationships between the buyers and sellers of health care, where physicians credibly can threaten to shift the locus of care to high-cost hospital settings, consolidate their practices into high-price specialty guilds, or drop out of the health plans' networks altogether. Benefit designs emphasizing consumer cost sharing are both too effective, pushing some patients to the brink of bankruptcy, and insufficiently effective, since a large fraction of total biopharmaceutical costs are incurred by patients who already have spent through their deductibles and annual payment limits.

THE GOAL OF SOCIAL POLICY WITH RESPECT to biopharmaceuticals is neither innovation nor cost control per se but, rather, an appropriate balance of access and affordability. Many countries delegate this balancing to governmental entities, which regulate prices, establish a formulary, impose consumer cost sharing, and create a uniform method of physician reimbursement and product distribution. The United States is delegating this balancing to multiple private insurers, leading thereby to a diversity of price levels, drug formularies, distribution channels, physician payment methods, and benefit designs.

The long-term consequences of this delegation of decision-making authority to private health plans are not yet clear. A pessimistic scenario would picture continued off-label and ineffective use, erosion of insurance coverage, and punitive consumer cost sharing. An optimistic scenario would be based on increased sophistication on the part of both insurers and biotechnology manufacturers. The effectiveness of insurers' strategies could grow over time as insurers invest in pharmaceutical expertise, improve coding and information systems, rationalize distribution channels, and migrate to less inflationary physician payment methods. The biopharmaceutical industry could respond by developing products supported by studies of comparative efficacy and cost-effectiveness and by marketing those products only through specialists with the relevant expertise and appropriate incentives. Between them, the insurers and manufacturers will decide whether the United States finds an acceptable balance between innovation and affordability or replicates in this technologically dynamic context the larger health care paradox of simultaneous excess and deprivation.

.....
This analysis was supported by the California HealthCare Foundation.

NOTES

1. Curascript Pharmacy, *2004 Specialty Pharmacy Management Guide and Trend Report* (Orlando: Curascript Pharmacy, 2005); Burrill and Company, *Biotech 2004: Life Sciences Back on Track* (San Francisco: Burrill and Company, 2004); Ernst and Young, *Beyond Borders: Global Biotechnology Report 2005*, http://www.ey.com/global/content.nsf/International/Biotechnology_Report_2005_Beyond_Borders (accessed 9 June 2006); and Medco Health Solutions, *Drugtrend Report 2004*, vol. 6, issue 1 (May 2004), 51-55, http://www.drugtrend.com/art/pdf/Drug_Trend_2004.pdf (accessed 9 June 2006).
2. J.C. Robinson, "Reinvention of Health Insurance in the Consumer Era," *Journal of the American Medical Association* 291, no.15 (2004): 1880-1886.
3. This paper was based on a review of the available literature on health plan strategies plus interviews with executives and managers with responsibilities for pharmacy services, medical management, contracting, pharmacy and therapeutics committees, specialty drug distribution, and other functions at Kaiser Permanente; WellPoint; UnitedHealthcare; and Blue Cross and Blue Shield plans in California, Pennsylvania, Oregon, Washington, and Minnesota. Additional information was obtained from interviews with biotechnology manufacturers, drug distributors, investment analysts, and industry consultants.
4. P.J. Neumann, "Why Don't Americans Use Cost-Effectiveness Analysis?" *American Journal of Managed Care* 10, no. 5 (2004): 308-312; and A.M. Garber, "Cost-Effectiveness and Evidence Evaluation as Criteria for Coverage Policy," *Health Affairs* 23 (2004): w284-w296 (published online 19 May 2004; 10.1377/hlthaff.w4.284).
5. In rheumatoid arthritis, for example, while the self-injected Enbrel was excluded from only 1 percent of formularies (and the office-infused Remicade was covered under traditional Medicare as incident to the professional practice of medicine), Humira was excluded from 20 percent and Kineret from 46 percent of formularies. E. Wang, Y. Werber, and R. Rapaport, "Biotechnology: Implications of Medicare Part D Formularies for Key Biotech Drugs" (New York: Citigroup Global Markets, 1 December 2005).
6. J.C. Robinson and J.M. Yegian, "Medical Management after Managed Care," *Health Affairs* 23 (2004): w269-w280 (published online 19 May 2004; 10.1377/hlthaff.w4.269).
7. BSC prior authorization for psoriasis requires diagnosis by a dermatologist or rheumatologist, age greater than eighteen (FDA label), moderate-to-severe disease for at least one year and covering a significant extent of body surface, attempted treatment but inadequate response to ultraviolet light therapy (unless contraindicated), treatment but inadequate response to disease-modifying drugs such as methotrexate or cyclosporine, and reevaluation after initial treatment of twelve weeks (compared with one year for rheumatoid arthritis).
8. The BSC prior authorization criteria include prescription by an allergist or pulmonologist; documented history of persistence for more than one year; prior use of standard therapies (Xolair should not be used as first-line therapy); inadequate response during the past year, as evidenced by asthma-related emergency room visit, inpatient admission, or unscheduled outpatient visit; high immunoglobulin level (as specified by the FDA); documented prior use of maximum tolerated inhaled steroids (FDA label); and restriction to nonsmokers. Approval is for six months, with subsequent extension if the patient has complied with the therapy regimen and shows evidence of improvement.
9. Some office-administered biologics may be reimbursed as a physician office supply item and not first routed for evaluation by the P&T committee.
10. G.P. Mays, G. Claxton, and J. White, "Managed Care Rebound? Recent Changes in Health Plans' Cost Containment Strategies," *Health Affairs* 23 (2004): w427-w436 (published online 11 August 2004; 10.1377/hlthaff.w4.427).
11. R.R. Gillies et al., "How Different Is California? A Comparison of U.S. Physician Organizations," *Health Affairs* 22 (2003): w492-w502 (published online 15 October 2003; 10.1377/hlthaff.w3.492).
12. B. Edelman, "Specialty Pharmacy Booms, but for How Long?" *Biotechnology Healthcare* 1, no. 1 (2004): 31-37; and Curascript Pharmacy, *2004 Specialty Pharmacy Management Guide and Trend Report*.
13. D. Kempner and T. Overmeyer, "The New Oncology Marketplace," *In Vivo: Business and Medicine Report* 18, no. 6 (2004): 64-70.
14. T.B. Gibson, R.J. Ozminkowski, and R.Z. Goetzel, "The Effects of Prescription Drug Cost Sharing: A Review of the Evidence," *American Journal of Managed Care* 11, no. 11 (2005): 730-740.
15. G. Claxton et al., *Employer Health Benefits: 2005 Annual Survey*, September 2005, <http://www.kff.org/insurance/7315/index.cfm> (accessed 9 June 2006).