Biologic Therapy Management

The Need for Value-Based Health Benefits Models

A peer-reviewed white paper by
THE BIOLOGIC FINANCE AND ACCESS COUNCIL

Sponsored by The Chatham Institute

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BFAC: A Valuable Resource for Third-Party Payers and Employer Purchasers

The emergence of biologic therapies is straining traditional models of health insurance and health care financing. During my decade of experience as a commercial and Medicare health plan medical director, I had to make difficult decisions every day. Biologic therapies and personalized medicine add yet another dimension of complexity to the challenges today’s managed care decision makers face. For patients, biologics offer benefits for improved quality of life, and are sometimes life saving. For payers and purchasers, the cost of biologics is provoking benefit design changes that include significant cost shifting to patients and attempts to control or limit the cost of these therapeutics to the plan or plan sponsor.

These issues must be addressed if employers are to continue to afford to offer health benefits to workers and their dependents. In developing this white paper, the Biologic Finance and Access Council (BFAC) examines the “value” of biologic therapies from the perspectives of various stakeholders, then applies those perspectives to issues they routinely face, such as access, affordability, benefit design, and the administration of biologics.

Rheumatoid arthritis is used as an example to illustrate the concepts described in the first three chapters, primarily because of RA’s prevalence in the working-age population, and because its treatment involves myriad medical and financial considerations. The final chapter applies issues discussed in the previous sections to theories about efficient administration and management of biologics — the complexities of which resonate across numerous conditions that affect working-age populations.

BFAC comprises thought leaders from large employers, national and regional health plans, and pharmacy benefit managers, as well as nationally regarded health economists, actuaries, benefit consultants, clinicians, patient advocates, and academicians. The council facilitates the exchange of ideas and rigorously analyzes research, empirical data, and other information regarding access to, current and future means of financing, and management of biologics. BFAC assists purchasers, payers, and policymakers in finding their own answers regarding the value and place for biologics.

This white paper is a framework for BFAC’s fully integrated approach to resolving difficult health care financing and benefit design issues. The council is primed with intellectual capital, health care financing and benefit design issues. The council facilitates the exchange of ideas and rigorously analyzes research, empirical data, and other information regarding access to, current and future means of financing, and management of biologics. BFAC assists purchasers, payers, and policymakers in finding their own answers regarding the value and place for biologics.

I am happy to facilitate that discussion.

I hope you find this document thought provoking and useful in your daily responsibilities.
Biologic Therapy Management:
The Need for Value-Based
Health Benefits Models

A peer-reviewed white paper by THE BIOLOGIC FINANCE AND ACCESS COUNCIL

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BFAC Co-chairs and Principal Authors

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The Biologic Finance and Access Council panel (see opposite page) had significant input in reviewing this content and in shaping the analyses at the end of each chapter. BFAC gratefully acknowledges the assistance of Jack Alan McCain Jr. in drafting this monograph.

This activity is supported by an educational donation provided by Amgen and Wyeth Pharmaceuticals. The material in this supplement has been independently peer reviewed. The supporters played no role in reviewer selection.

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Target audience
This program is targeted to medical directors, pharmacy directors, and other managed care health care professionals, as well as corporate medical directors and other employer health benefits decision makers.

Overview
In response to accelerating health care costs, payers and purchasers are shifting the cost burden to patients. This has created access barriers—particularly for biologic and targeted therapies, for which the cost burden can be substantial. The potential benefits associated with these therapies warrant examination in the context of health care coverage, financing, access, and administration.

Medications developed through biotechnology research do not fit neatly within traditional benefit-design structures. The cost of biotech injectable medications often requires significant out-of-pocket expenditures. Higher cost sharing under prescription drug and medical plans has a documented effect on patient access to care. The unintended consequences of limiting access and reimbursement for biologics could reverse well-meaning attempts to control unnecessary health care resource utilization, and to reduce total health care expenditures and improve employer productivity.

Educational objectives
After reading this publication, participants will be able to:
• Define the societal issues pertinent to patient access to appropriate health care treatment options.
• Evaluate the role and value of biologics for chronically ill patients.
• Advocate for policies surrounding access to, reimbursement for, and financing of biologics.

Accreditation and designation
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ACPE Universal Program Number (UPN):
812-000-08-009-H01-P
Release Date: March 15, 2008
Expiration Date: March 15, 2009
Medium: Journal supplement

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The faculty of this program and the editorial staff of this monograph has disclosed the following: Christopher V. Goff, Joel Hoffman, F. Randy Vogenberg, Steven R. Peskin, Michael D. Dalzell, and Jack Alan McCain Jr., no conflicts of interest to report.

Program sponsorship and support
This activity is jointly sponsored by The Chatham Institute and BioCommunications LLC, and is supported by an educational donation provided by Amgen and Wyeth Pharmaceuticals.
The history of health insurance in the United States is complex and dynamic, involving shifting alliances among numerous stakeholders — organized medicine, hospitals, labor unions, corporations, government, insurers, and patients. Over the years, these shifts have altered the makeup of insurance products, but the nature of insurance remains the same: To protect the beneficiary from infrequent, high-cost, catastrophic events. Biologic therapies, also known as biopharmaceuticals and specialty drugs, among other terms, would seem to fit into the rubric of insurance coverage; they are used relatively infrequently and they are costly. Yet insurers and plan sponsors do not universally cover them. Where coverage does exist, it often involves high cost sharing, potentially shutting off access to biologics for those who would likely benefit from them.

From a business standpoint, premium costs must be controlled to make benefits available and to keep them affordable. But if the cost of biologics leads plan sponsors to place severe limitations on their coverage, then purchasers must ask themselves why this is necessary. What do their insurance premiums cover now, and what is the value of those benefits? How is the value equation changed when biologics are added to the mix? For employers, the benefits of efficient coverage — which can include reduced disability, greater productivity, and employee satisfaction — go well beyond what can be measured on a P&L statement.

This publication examines these issues in the context of coverage of biologics.

Policies governing coverage of biologics often are inconsistent with the purpose of insurance: to protect the insured against a catastrophic event.

The United States may not be getting good value for its health care dollars.
It should be noted that although the phrase *health insurance* is engrained in the lexicon, most of the financial products associated with it today are a substantial departure from the basic concept of insurance. Insurance spreads among many people the risk of some high-cost event that occurs predictably (albeit infrequently) in a very large population but rarely in an individual. Health insurance, strictly speaking, does not protect a subscriber against expenditures for regularly occurring, low-cost events, such as routine physicals and preventive screenings. This was true of most pre-managed care indemnity plans. Today’s comprehensive benefit plans, which promote population health by encouraging use of primary care and preventive services, are not insurance in the purest sense. Kling (2007) makes a distinction between *insurance*, which pays for treatments that are “unavoidable [or] prohibitively expensive, or for illnesses that occur relatively rarely,” and *insulation*, which covers “relatively low-cost services” and “treatment that is commonplace or discretionary.” The difference is analogous to auto insurance, which protects an owner from collision, theft, or damage to a car (insurance) but does not pay for oil changes or state safety inspections (insulation).

Actuaries calculate the degree of risk borne by an individual or a population, then determine the amount of money required from premiums to cover expected liabilities. In some cases, actuaries may conclude that the risk is too high and the potential payout too great, or that a certainty exists that a given individual or group is uninsurable in whole or in part. Hence, a policy may deny services for some “pre-existing” condition, or simply deny coverage outright for a person in a high-risk occupation. Many population-health products, including most employer-sponsored managed care plans, are prohibited from denying coverage on the basis of one’s health, and thus are not classic risk-based insurance products. Rather, they are closer to European-style universal care programs, in which healthy young adults subsidize the care of older, less healthy people.

**Employer-based coverage**

In the United States, employment-based health insurance has been a dominant force in health care finance for decades. Today, according to the Census Bureau, 60 percent (177 million) of Americans have employment-based health insurance (Figure 1). However, rising employee health care costs that drive higher health insurance premiums, the requirement that employers take a liability on their financial statements for retiree health care costs, and the migration of retiree outpatient prescription drug benefits to Medicare Part D have precipitated a slow decline in the breadth of employer-based health coverage (Cutler 2003, Poisal 2007).

Still, employment-based health insurance remains — and will continue to be — a substantial component of the U.S. health care system. This was made clear by the actions of various candidates in the 2008 presidential campaign. As governor of Massachusetts, Mitt Romney signed into law what he called a “personal responsibil-
Moral hazard refers to one’s use of additional health care services thanks to the presence of health insurance.

The managed care backlash relaxed access to care. The effect on moral hazard is uncertain.

You’re insured so when you need a bypass or get hit by a bus, we’re there in your hour of need. That’s what insurance is. What do Mr. and Mrs. America expect from their coverage? If it is, “Once I have insurance, I’ll never spend another dime out of pocket,” we can live with that. But the premiums need to reflect that.

— Allan Korn, MD, Blue Cross Blue Shield Assn., in Managed Care (1999)

Moral hazard

Health was long regarded as uninsurable because of two perceived problems: Adverse selection and moral hazard. Adverse selection holds that the people most likely to buy health insurance are the people most likely to use it. Further, the amount of health insurance people are willing to buy is directly related to the amount they will use. Moral hazard1 is the phenomenon by which the mere presence of insurance is thought to promote inefficient, if not “immoral,” behavior that results in unnecessary use of the health benefits. Actuarily speaking, moral hazard occurs on two levels — when first-dollar coverage is provided and when out-of-pocket maximums have been reached.

Moral hazard1 has been the subject of great debate since the emergence of the comprehensive benefit plans commonly offered to employees today. These plans were originally envisioned as a way to save downstream medical costs by providing benefits for prescription drug coverage and for annual check-ups, routine screenings, and other forms of preventive care. To control costs and minimize moral hazard, incentives to use primary care and to fill prescriptions were coupled with tight controls on specialist access and costly procedures. The managed care backlash of the late 1990s led to the elimination of many utilization controls employed in these plans, but the comprehensive nature of the coverage was maintained. As a result, enrollees were given access to most health care services or products — as long as they were willing to pay for them in the form of higher copayments and coinsurance, until out-of-pocket maximums were reached.

But if patients perpetuate moral hazard by consuming more health care, the behavior of health care providers should not be overlooked, either. As a recent article in Consumer Reports put it, “Insured? You’re money in the bank to the health-care system” (Consumers Union 2007). Among the tools for influencing provider behavior are capitation, evidence-based treatment guidelines, and utilization review (Table 1, next page). These behavior-modification techniques are intended to make physicians think about the “medical necessity” of a service, thus making the system more efficient (Bergthold 1995).

1 Moral hazard is a term frequently encountered in the health economics literature. Insurers and actuaries often use the term induced utilization to mean the same thing.
Insurance is offered as an alternative to higher wages, and is not contingent on employer generosity.

2 The Stabilization Act of 1942 limited wage increases during World War II, but allowed businesses to offer employees health insurance in lieu of wage increases.

The cost-containment tactics employed in managed care (discussed in greater detail in Chapter 3) are based on the conventional theory of consumer demand for insurance — essentially, that demand for insurance is a demand for certainty, for risk avoidance. Some people apparently regard insurance premiums as a personal investment, however, and view any benefits received as a return on their investment. People with this attitude express a preference for policies that cover common ambulatory services while providing moderate coverage for the rare but far more expensive catastrophic events (Pauly 2007). Should this be the purpose of health insurance?

To be sure, such scenarios as employee demands for formulary coverage of erectile dysfunction drugs and physicians performing unnecessary procedures on well-insured patients helped to create the perception that moral hazard is negative. But is all moral hazard inherently bad? Can moral hazard be stratified into types that are efficient and inefficient? If insurance enables access to costly but potentially life-saving treatments, can this result in benefits to business and society?

Cost sharing
Economists agree that employees, not employers, are harmed by high health care costs. That’s because, from an economic perspective, the money employers spend on behalf of employees for health insurance is actually money that the employees could have received as wages.

Pauly (1997) condenses reasons for demand for health insurance to a single theorem: “Employers offer insurance when their employees demand it and are willing to pay for it with wage offsets.” He contrasts the economic perspective with the prevailing noneconomic view of health insurance, which holds that employers offer insurance when they can afford it and do not offer it when they cannot.

At the level of the national economy, it is argued that health insurance expenditures erode profits, cause the prices of products to rise, and put U.S. companies at a competitive disadvantage relative to countries with lower health care costs. The affordability argument is embraced by employers large and small, and by politicians and journalists, too. In rebuttal, Pauly cites a rhetorical device commonly used to demonstrate how the cost of health care coverage allegedly causes the United States to suffer in international trade. This example compares the cost of health insurance involved in the production of a U.S. automobile with the cost of the steel in the vehicle or with the cost of health insurance involved in making a Japanese auto. No matter what kind of labor conditions are envisioned, says Pauly, higher health benefit costs in the auto industry do not affect corporate profits — they only displace wages (Pauly 1997). This means that if employees want health insurance that provides first-dollar coverage, financing for routine services and lifestyle-enhancing products, and mints on the hospital pillow, they can have it — in exchange for lower wages and higher out-of-pocket costs.

Cost sharing is often invoked as a means for employers to keep health insurance affordable. The first major study to look at the effects of cost sharing — and one that is commonly cited as a reason for using cost sharing to counter moral hazard — is the Rand Health Insurance Experiment (HIE), conducted between 1974 and 1982. Intended to determine whether cost sharing should be used in Medicaid, the HIE enrolled about 2,000 families whose members were under the

### Table 1

<table>
<thead>
<tr>
<th>Tools for reducing excess health care utilization</th>
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<tr>
<td><strong>Demand-side tools</strong></td>
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<tr>
<td>Coinsurance</td>
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<td>Deductibles</td>
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<td>Step therapy</td>
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<td>Utilization review</td>
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The stabilizing Act of 1942 limited wage increases during World War II, but allowed businesses to offer employees health insurance in lieu of wage increases.
The Rand Health Insurance Experiment showed that the more one pays for health care, the fewer services used.

Cost sharing had a minimal impact on expenditures overall ... because the majority of employees used few health care services. Those with serious health problems who used the most services were too concerned about their own health to be deterred from seeking care by high deductibles and copayments.

— JIL QUADAGNO, PhD, One Nation Uninsured (2005)

age of 65 and who earned less than $25,000 per year (equal to $80,312 in 2006 dollars). Families were randomly assigned to receive free care or coinsurance programs at rates of 25, 50, or 95 percent (Keeler 1982).

HIE demonstrated that demand for health care is elastic — that is, responsive to changes in price: The less a family paid, the more health care services it used. There was little variation in elasticity from service to service, with the exception of mental health services (greater elasticity) and inpatient medical care for children (no elasticity) (Feldman 1991). Elasticity was found to be related to income, with poorer families more likely to reduce health care consumption than wealthier families. Most of this reduction took the form of failure to see a health care professional in the first place. Participants were unable to distinguish services considered by physicians to be more essential (e.g., treatment of pneumonia) from those regarded as less essential (e.g., treatment of constipation) — they just reduced consumption in general.

Higher cost sharing was associated with decreased use of preventive care and inappropriate use of emergency departments and antibiotics, but did not affect hospital admissions. In general, if the goal of cost sharing is to discourage the use of ineffective health care services while promoting the use of effective services, HIE demonstrated that it doesn’t work very well.

Because the HIE showed that cost sharing reduces medical spending, many employers and insurers quickly turned to increased cost sharing during the 1980s — deploying the now familiar tools of managed care: copayments, coinsurance, and deductibles. It was reasoned that these tools would reduce employer costs and mitigate the potential for moral hazard, even as employer offerings were shifting from indemnity products to HMOs and benefit packages were becoming more comprehensive.

In the years that followed, studies of the utilization effects of cost-sharing tools corroborated the HIE findings. Cherkin (1989) found that the introduction of a $5 copayment resulted in a substantial reduction in office visits. Selby (1996) documented a similar reduction in demand when copayments were imposed on ER use. A study of the emergence of “incentive-based,” three-tier formularies found that some patients stopped buying drugs they used to manage chronic illnesses (Huskamp 2003). Other studies that measured the effects of reduced consumption on health outcomes reported mixed results; fewer office visits appeared not to affect health status, but access limitations posed by higher drug copayments did more harm than good for patients with chronic conditions (Gruber 2006).

A recent study suggested that when patients are presented with a life- or livelihood-threatening illness, cost is less of a barrier. Goldman and colleagues at Rand Health analyzed pharmacy and medical claims from more than 1 million people with primary diagnoses of cancer, kidney disease, rheumatoid arthritis (RA), or multiple sclerosis (MS). Higher copayments for specialty drugs resulted in utilization reductions of only 1 to 21 percent, depending on the therapy — a far smaller reduction than that documented for traditional, less-expensive phar-
Price of a treatment appears to be less of an object when a person faces a life-threatening illness.

Insurance may enable consumption that benefits society — depending on what resources are consumed by whom.

Societal effects

In the midst of the debate leading up to the enactment of Medicare and Medicaid, Arrow published an article arguing that if consumers were rational about use of services, risk averse, and charged actuarially fair premiums, then the case for government-supported expansion of health insurance was overwhelming. This is because the certainty of loss payouts versus premium collections would benefit consumers and the economy (Arrow 1963). In 1968, Pauly responded to Arrow’s article with the observation that because insurance lowers the price of health care to consumers but not the cost of producing health care, moral hazard results in a loss of prosperity (Figure 2). If so, Pauly wrote, it follows that excess use of health services resulting from the widespread availability of health insurance should be reduced to decrease welfare loss (Pauly 1968).

Pauly’s influential paper led most economists to believe that growth in health care expenditures stemmed from consumption of too much marginal care (Nyman 2003), and the Rand HIE seemed to confirm that cost sharing was an effective tool for combating moral hazard. Fifteen years later, Pauly clarified his 1968 remarks, stating that what he had in mind were “routine physicians’ services, prescriptions, dental care, and the like” — not the serious, expensive care that accounts for most health spending: “The relevant theory, empirical evidence, and policy analysis for moral hazard in the case of serious illness has not been developed” (Pauly 1983).

Does this suggest that high-cost products and services, such as biologics and their administration, do not necessarily represent moral hazard? In time, studies that document clinical outcomes and productivity involving people who receive biologic therapies will answer this question. In the aforementioned Rand study of the effects of cost sharing on specialty pharmaceutical utilization, Goldman effectively separated the demand for specialty pharmaceuticals from moral hazard, arguing that from an insurer’s standpoint, it makes “little or no economic sense” to deny coverage of specialty therapies to the relatively small portion of plan members who could benefit from them. If future studies document a positive return on investment (e.g., longer life, better quality of life, higher productivity, reduced disability) in biologic treatments, then Goldman’s assertion could prove prescient. This sort of analysis, however, will take years — until which time stakeholders will need benchmarks for judging the value of biologic therapies and insurance tools for allocating them to those who would benefit the most.

[Pauly’s 1968 paper] is behind most policies directed at containing health care costs in the U.S. and around the world — for example, the demand-side policies of raising coinsurance rates and deductibles, and the supply-side policies of imposing utilization review, bundled payments, and managed care, in general.

**“Efficient” moral hazard**

Nyman (2003) has presented a new theory of consumer demand for health insurance that suggests that the conventional wisdom about moral hazard is wrong. Nyman argues simply that consumers demand health insurance not to avoid uncertainty but rather, if they become ill, to secure an income transfer from those who remain healthy. The income transfer occurs via reductions in one’s out-of-pocket costs of medical care. Instead of leading to a welfare loss, the net effect of voluntary health insurance, Nyman says, is increased welfare for society because consumers remain productive and contribute to the economy.

![Diagram of moral hazard welfare loss](image)

The market price of medical care is shown as $P=mc$. If the consumer is insured, the cost of care is reduced, even as far as zero ($P=0$). Moral hazard — health care consumption owing to the presence of insurance — is illustrated in the striped area; at the far right, $bMi$ represents zero cost sharing (100% insurance coverage). The value of the moral hazard is depicted in green, below the demand curve; the costs that exceed the value of the moral hazard (red and white striped areas) represent a welfare loss.

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**ADAPTED FROM NYMAN 2003**

Legend:
- $M$ — medical care
- $Mu$ — consumption without insurance
- $Mc$ — consumption with coinsurance
- $Mi$ — consumption with insurance
- $P$ — price
- $P=0$ — price of medical care with insurance
- $P=mc$ — marginal cost (market price of medical care)
- $D$ — demand curve

The focus on moral hazard suggests that the changes we make in our behavior when we have insurance are nearly always wasteful. Yet, when it comes to health care, many of the things we do only because we have insurance ... are anything but wasteful and inefficient. In fact, they are behaviors that could end up saving the health-care system a good deal of money.

from other types of insurance because most of the services covered by health insurance are desired only by the ill, Nyman observes. Moral hazard exists — people with health insurance do consume more health services as a result of having the insurance — but most of the moral hazard, he says, is efficient rather than inefficient.

The major problem Nyman finds with managed care is that as it strives to reduce inefficient moral hazard, it also reduces efficient moral hazard — the insurance-enabled consumption of health care that enables an ill person to receive life-saving health care services that otherwise would be unaffordable:

Coinsurance rates are too crude a tool to use to reduce health care costs because they are not focused on inefficient moral hazard alone. While imposing a 50% coinsurance rate … clearly reduces consumption, it would also reduce welfare to the extent that it reduces the utility from consumption of efficient care more than it raises utility from consuming less efficient care.

Nyman’s point is borne out by a 2007 report released by the Integrated Benefits Institute, a not-for-profit organization supported by employers, insurers, providers, and pharmaceutical companies (IBI 2007). IBI studied up to 3 years of claims data (medical, pharmacy, short- and long-term disability, and workers’ compensation) for 5,483 workers who were diagnosed with RA and who missed work days because of their condition. These employees were drawn from a database that included more than 1 million covered lives among 17 employers.

In the IBI study, 55 percent of the workers with RA failed to fill even one prescription for a disease-modifying antirheumatic drug (DMARD), including

### TABLE 2 A proposed redistribution of risk

<table>
<thead>
<tr>
<th>Type of health care</th>
<th>Examples</th>
<th>Risk bearer</th>
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<tbody>
<tr>
<td><strong>Catastrophic care</strong></td>
<td>Long-term skilled nursing facility care</td>
<td>Government</td>
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<tr>
<td></td>
<td>Lengthy hospitalizations</td>
<td></td>
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<td></td>
<td>Inpatient mental health care</td>
<td></td>
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<tr>
<td></td>
<td>Very expensive medical procedures, drugs, devices</td>
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<tr>
<td><strong>Noncatastrophic care</strong></td>
<td>Acute care</td>
<td>Private insurance</td>
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<tr>
<td></td>
<td>Management of chronic conditions</td>
<td>Government</td>
</tr>
<tr>
<td></td>
<td>Most prescription drugs and durable medical equipment</td>
<td></td>
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<tr>
<td><strong>Preventive services</strong></td>
<td>Immunizations</td>
<td>Government (for those not already covered through employment-based insurance or Medicaid)</td>
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<tr>
<td></td>
<td>Preventive screenings</td>
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<td></td>
<td>Prenatal care</td>
<td></td>
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<td></td>
<td>Well-baby physicals</td>
<td></td>
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<tr>
<td><strong>Predictable low-cost services and products</strong></td>
<td>Routine primary care (except for low-income families)</td>
<td>Out of pocket</td>
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<tr>
<td></td>
<td>Routine dental care</td>
<td></td>
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<td></td>
<td>Eyeglasses</td>
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<td></td>
<td>OTC drugs</td>
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<tr>
<td><strong>Cosmetic procedures</strong></td>
<td>Breast enlargement</td>
<td>Out of pocket</td>
</tr>
<tr>
<td><strong>Lifestyle care</strong></td>
<td>Wrinkle reduction</td>
<td>Private insurance</td>
</tr>
</tbody>
</table>

**SOURCE:** JOST 2007
Employers that shift too many health care costs to workers may lose more money than they save.

The knee-jerk reaction for a lot of employers is trying to extract more member [cost] share because of the cost of a drug. I've seen employers create a fourth tier specifically for biotech drugs. It flies contrary to the whole premise of value-based design.


biologic DMARDs, and 36 percent failed to fill at least one script for a symptom-relieving drug. Script-filling behavior was related to increases in copayments: Increasing the copayment by $20 reduced the share of workers filling at least one script for a DMARD or a symptom-relieving drug by 35 percent and 84 percent, respectively. The lesser elasticity in demand for DMARDs was attributed to workers’ awareness of the ability of these drugs to affect the course of their disease — a finding consistent with that of Goldman mentioned above — whereas the greater elasticity in the demand for symptom-relieving drugs pointed to the availability of over-the-counter alternatives. Had the 55 percent of workers who did not fill scripts for DMARDs filled their scripts at the same rate as those who did fill them, IBI estimates that their employers would have saved $4.4 million in lost productivity: $3.2 million from a reduction in the incidence of short-term disability and $1.2 million from a decline in the duration of the disability. This represents a 26 percent reduction in the $17.2 million in lost productivity attributed to these workers at baseline (IBI 2007).

According to Nyman, an optimally designed health insurance policy would use cost sharing to control inefficient moral hazard, but would not impose any such controls on the efficient portion of moral hazard. Because current practices are unable to focus on inefficient moral hazard alone, it might be more practical, he suggests, to construct moral hazard profiles for specific illnesses. If illnesses that are life-threatening and expensive to treat are associated with efficient moral hazard, then no cost sharing should be employed for routine care or expensive procedures (Nyman 2003). This is the underlying premise of what has become known as value-based benefits design, which is explored in greater detail in Chapter 3.

Others also have proposed insurance mechanisms to address the separation of efficient and inefficient moral hazard. Jost (2007) suggests that a public-private system of risk bearing could be developed (Table 2) to address what he regards as the major problem in our health care system: affordability. “It is not simply that health care is unaffordable for the few who experience catastrophic costs — insurance can take care of that. It is rather that health insurance is unaffordable for many,” he writes. Separately, Aaron (2005) has proposed a form of near universal coverage, not only to address the problem of affordability, but also to provide a mechanism for reducing everyone’s use of low-benefit care. Implementing such a plan effectively, he points out, requires much greater investment in studies to determine what works and what does not.

In other words, which treatments provide true value? Chapter 2 offers some perspectives on value to help to answer this question.

**BFAC: OUR ANALYSIS**

This chapter makes several points that are directly relevant to the financing of biologics.

First, biologics — which are used by relatively few patients — work well with the notion that in its purest form, insurance is an instrument for spreading the

A reasonable system of cost sharing should be accompanied by research to determine interventions that provide the greatest benefit.
Cost sharing should not be directed against the efficient portion of moral hazard. The need for a costly biologic is an event against which insurance should provide the policyholder with financial protection.

Moral hazard can be efficient if insurance helps a person to achieve better health and productivity.

Risk of predictable-but-rare, high-cost events. Assuming that biologics are prescribed appropriately, it follows that attempts to control utilization of biologics at the expense of the patients who would benefit from them would run counter to the basic purpose of insurance.

Many Americans today have a form of health insurance that is far from pure and serves as insulation, as Kling calls it, thus helping policyholders finance routine and inexpensive health care services. Pauly’s assertion that some people regard their health benefits, no matter how small, as a return on their premium investments is true — this does happen, and enabling this attitude is one of the primary reasons insurance costs are rising.

It is commonly believed that higher insurance costs erode corporate profits. But if employer-provided health insurance is a part of total compensation, and if total compensation responds to market forces, then the total compensation offered today is the “right” amount because the market can bear it. The balance between cash and benefit compensation is precarious, and enacting higher employee cost sharing to maintain that balance is a poor substitute for getting more value from the share of dollars spent on health benefits. If judicious use of biologics adds value to health care, enables greater productivity, and benefits society in general, then insurers and employers should make them available to patients who are likely to benefit from them, without resorting to high cost sharing. This can be achieved without higher health insurance costs, though possibly at the expense of eliminating insulation for many lower-cost or routine services.

Second, this chapter examines the concept of moral hazard, which affects spending on biologics. In its conventional form, moral hazard says people who have insurance are likely to use it even if they don’t really need to use it. Tempted by the availability of insurance, the theory goes, people act inefficiently and use it unnecessarily — as if taking an extra piece of pie from the all-you-can-eat buffet. The Rand HIE seemed to confirm this, but since then a contrary view of moral hazard has emerged, in which it is acknowledged that, yes, people with health insurance do consume more health care, but the moral hazard this fosters can be efficient. Moral hazard benefits society when better health and higher productivity result from treatment that otherwise would have been unavailable to someone without the means to finance that care.

Third, Nyman makes an important observation on the use of cost sharing, as applied to biologics. Cost sharing is used — appropriately — to control inefficient moral hazard such as routine services, but it should not be directed against the efficient portion of moral hazard. The problem with today’s managed care cost-control tools, such as coinsurance and high copayments, is that they reduce all moral hazard, whether inefficient or efficient. One might argue that a truly immoral action would be to use cost sharing as a blunt instrument to curtail the use of biologics in all patients without regard to the appropriateness of the treatment.

This chapter presents evidence, provided by Goldman, that the demand for specialty pharmaceuticals used to treat cancer, MS, kidney disease, or RA is relatively inelastic. When cost sharing is doubled, consumption of traditional pharmaceuticals spending drops as much as by half, but use of specialty pharmaceuticals decreases by much lesser amounts, ranging from a mere 1 percent (cancer) to 21 percent (RA). Further, the study by the IBI mentioned in this chapter shows that when higher copayments dissuade employees with RA from
filling prescriptions for DMARDs, short-term disability increases and productivity diminishes.

The most responsible action on the part of purchasers and payers would be to focus their efforts on identifying patients for whom biologics are appropriate therapy, rather than trying to discourage their use across the board. Finally, all parties should bear in mind that the price of biologics, high though it may appear, is nothing more than the justifiable price of medical innovation, now and in the future.

References
Consumers Union. Treatment traps to avoid. Consumer Reports. 2007;Nov:12–17.
To get to greater efficiency in health care, we will need a more serious commitment to funding research on appropriate care and on the evaluation of medical technologies, and we will need to adopt health care practices that promote value.

— Alan Garber, MD, PhD, Health Affairs, 2007

A biologic is defined in various ways, depending on who is using the term. As a group, biologics often are referred to as biopharmaceuticals, targeted therapies, specialty pharmaceuticals,1 and high-cost, high-maintenance drugs. A good working definition of biologics is drugs made from living organisms and genetically engineered to produce specific therapeutics. The majority of these drugs are injected or infused, although some oral forms have been developed. In contrast, conventional or traditional prescription drugs are produced through chemical synthesis, and most are taken orally. The Centers for Medicare & Medicaid Services defines specialty drugs as those that regularly cost $500 or more for a 30-day supply (CMS 2006).

Biologics on the market today are designed to manage cancers, rare diseases such as Gaucher disease, and a handful of hard-to-treat chronic conditions, such as intestinal disorders, psoriasis, multiple sclerosis, and rheumatoid arthritis (RA). Biologics also are being developed for common chronic conditions, such as diabetes and heart disease. Biologics are distributed by specialty pharmacies, because they are time sensitive or need special handling, such as refrigeration or freezing, and thus require a different distribution channel.

The costs involved in providing these drugs to patients, the high costs that patients themselves must incur, and questions about the efficacy of these products have raised critical issues about the value of biologics.

U.S. health care spending

As a percentage of GDP, U.S. health expenditures have increased dramatically since 1960 and are projected to continue to increase. Annual health care spending reached $2.2 trillion in 2007, or 16.3 percent of GDP, and is expected to grow at an annual rate of 6.7 percent during the next decade, reaching $4.3 trillion by 2017 — when it will account for 19.5 percent of GDP (Keehan 2008).

With the exception of a span of 3 years (1992–1994), every year from 1978 through 2003 produced double-digit increases in prescription drug spending (Catlin 2008). Although annual increases since then have fallen back to the single-digit range, drug spending is poised again to become one of the fastest-growing components of U.S. health care spending. Already, the seeds for this trend have sprouted; the implementation of Medicare Part D, new indications for existing drugs, and the increased use of specialty drugs combined to accelerate drug expenditure growth dramatically in 2006 — up 8.5 percent, compared with a 5.8 percent growth rate in 2005 (Catlin 2008). Over the next decade, drug spending
is projected to grow at an average annual rate higher than those projected for physician, hospital, and nursing home care (Keehan 2008).

Increasingly, growth in drug spending will be propelled by the greater use of biologics. The U.S. Food and Drug Administration approved only eight new biopharmaceuticals from 2005 through 2007, suggesting that additional indications for existing products (see Figure 1), and not new brands, account for the majority of increased specialty drug use (Express Scripts 2007). In time, however, new products are expected to contribute more heavily to utilization trends, given the volume of biopharmaceuticals in development (Figure 2, page 16). Many of these new products, too, will be studied for additional uses — accelerating utilization trends.

The upshot is that the share of drug spending attributed to biologics is expected to increase dramatically. Although data that quantify this vary, the trend is unmistakable: Specialty drugs accounted for 10 to 20 percent of prescription drug spending in 2006 (Medco 2007, Express Scripts 2007); Express Scripts predicts that by 2010, they will account for more than one fourth of all drug spending (Figure 3, page 16); and Aon Consulting has estimated that biologics’ share will hit 37 percent by 2020 (Sipkoff 2006). For the short term, according to a report commissioned by the Biotechnology Industry Organization, biologics approved after 2005 will increase total health care costs for private commercial payers by slightly more than 1 percent ($5 per member per month) by 2011 (Pyenson 2007).

Those biologics expected to experience the greatest growth are the monoclonal antibodies, such as trastuzumab (Herceptin), infliximab (Remicade), bevacizumab (Avastin), adalimumab (Humira), and rituximab (Rituxan) — all of which treat either chronic conditions or cancer (Datamonitor 2007). Although sales of traditional drugs are predicted to grow at a compound annual growth rate (CAGR) of only 0.6 percent during this period, Datamonitor predicts a CAGR of 14 percent for monoclonal antibodies.

**FIGURE 1 Biologic drug approvals lag new indications**

*Increased use of biologic drugs comes primarily from new indications for existing products*

<table>
<thead>
<tr>
<th>Year</th>
<th>BLA approvals*</th>
<th>New indications for existing products</th>
</tr>
</thead>
<tbody>
<tr>
<td>1997</td>
<td>19</td>
<td>13</td>
</tr>
<tr>
<td>1998</td>
<td>25</td>
<td>18</td>
</tr>
<tr>
<td>1999</td>
<td>20</td>
<td>17</td>
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<tr>
<td>2000</td>
<td>32</td>
<td>2</td>
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<tr>
<td>2001</td>
<td>25</td>
<td>20</td>
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<td>2002</td>
<td>29</td>
<td>7</td>
</tr>
<tr>
<td>2003</td>
<td>31</td>
<td>6</td>
</tr>
<tr>
<td>2004</td>
<td>35</td>
<td>5</td>
</tr>
<tr>
<td>2005</td>
<td>38</td>
<td>2</td>
</tr>
<tr>
<td>2006</td>
<td>39</td>
<td>4</td>
</tr>
</tbody>
</table>

*Biologic license application approvals only. The FDA’s Center for Drug Evaluation and Research also approves some specialty drugs considered “biologics” under the new drug approval (NDA) process. The FDA approved 2 BLAs in 2007.

**The share of drug spending attributable to biologics will increase 35 percent in 4 years.**

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2 These statistics and those in Fig. 1 represent Center for Drug Evaluation and Research biologic license approvals. A handful of new molecular entities approved by CDER from year to year — such as lenalidomide (Revlimid, approved in 2005) and dasatinib (Sprycel, approved in 2006) also are considered specialty drugs.
**FIGURE 2** Biologic product development soars 29 percent in 2 years

A robust and fast-growing pipeline suggests that the rate of biopharmaceuticals reaching the market will increase in the next few years. In 2004, 324 biologic products were in development; by 2006, that number had risen to 418 biologic products in development.

**Biotech medicines in development, 2006**

By therapeutic category*

<table>
<thead>
<tr>
<th>Therapeutic Category</th>
<th>2004</th>
<th>2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer/related conditions</td>
<td></td>
<td>50</td>
</tr>
<tr>
<td>Infectious disease</td>
<td>22</td>
<td>44</td>
</tr>
<tr>
<td>Autoimmune disorders</td>
<td></td>
<td>22</td>
</tr>
<tr>
<td>AIDS/HIV</td>
<td></td>
<td>17</td>
</tr>
<tr>
<td>Cardiovascular disease</td>
<td></td>
<td>15</td>
</tr>
<tr>
<td>Neurologic disorders</td>
<td></td>
<td>14</td>
</tr>
<tr>
<td>Diabetes/related conditions</td>
<td></td>
<td>13</td>
</tr>
<tr>
<td>Digestive disorders</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>Respiratory disorders</td>
<td></td>
<td>9</td>
</tr>
<tr>
<td>Blood disorders</td>
<td></td>
<td>7</td>
</tr>
<tr>
<td>Genetic disorders</td>
<td></td>
<td>6</td>
</tr>
<tr>
<td>Skin disorders</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>Eye conditions</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>Growth disorders</td>
<td></td>
<td>9</td>
</tr>
<tr>
<td>Transplantation</td>
<td></td>
<td>7</td>
</tr>
<tr>
<td>Others</td>
<td></td>
<td>6</td>
</tr>
</tbody>
</table>

* Numbers add up to more than 418 because some are listed in more than one category.

**Growth in the pipeline, 2004–2006**

By product category†

<table>
<thead>
<tr>
<th>Product Category</th>
<th>2004</th>
<th>2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antisense</td>
<td>14</td>
<td>20</td>
</tr>
<tr>
<td>Cellular therapy</td>
<td>11</td>
<td>21</td>
</tr>
<tr>
<td>Gene therapy</td>
<td>7</td>
<td>16</td>
</tr>
<tr>
<td>Growth factors</td>
<td>10</td>
<td>9</td>
</tr>
<tr>
<td>Immune-based therapy</td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>Interleukins</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Monoclonal antibodies</td>
<td>23</td>
<td>76</td>
</tr>
<tr>
<td>Recombinant hormones/proteins</td>
<td>43</td>
<td>90</td>
</tr>
<tr>
<td>Vaccines</td>
<td>62</td>
<td>90</td>
</tr>
</tbody>
</table>

†Categories with 5 or fewer products in development not shown.

**FIGURE 3** Specialty drug spending will almost double over 4 years

The share of total drug spending attributable to biologics will increase by 35 percent

<table>
<thead>
<tr>
<th>Year</th>
<th>Specialty</th>
<th>Nonspecialty</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>$54</td>
<td>$221</td>
</tr>
<tr>
<td>2010</td>
<td>$99</td>
<td>$284</td>
</tr>
</tbody>
</table>

SOURCE: EXPRESS SCRIPTS 2007

By 2011, employer spending for biologics is projected to total $9.80 PMPM—$5.00 for agents approved after 2005 and $4.80 for existing biologics, including their expanded indications (Pyenson 2007). Leaving aside any cost-sharing mechanisms that might apply, the projected increase attributed to biologics will be nearly equivalent to combined PMPM spending for chiropractic care and vision exams (Pyenson 2007). Over the longer term, as more biologics are developed for more diseases and common chronic conditions (see “Magnitude of Chronic Conditions,” left), spending patterns probably will differ considerably.

Determining health care value

Share of GDP and other measures of health care spending do not provide insight into the value of health care. Assessing value is difficult, because value is subjective. For example, patients might find value in drugs that allow them to achieve a higher quality of life. Employers might see more value in drugs that improve on-the-job productivity. A pharmacy director might find value in a drug that reduces spending in the pharmacy budget. Pharmaceutical companies might find value in drugs that are widely accepted by physicians, patients, and insurers. To a physician, a valuable drug might be one that makes the patient feel better and improves measurable clinical outcomes. The physician also might want to use the drug regarded by peers as best in class for a population, regardless of cost.

Calculating the value of health care requires weighing these biases against the direct and indirect costs of care. The primary component of indirect costs usually is lost productivity. In a simple cost-identification analysis, direct and indirect costs are used to calculate the total cost of a medical condition or treatment. This generates information about how much cost the health system, employer, or other purchaser is incurring, but it isn’t helpful in deciding whether there is value in the treatment. Decision makers, therefore, often turn to the following types of economic analyses for guidance in reconciling disparate conceptions of value (Table, page 20).

Cost-minimization analysis (CMA). If there is evidence suggesting that two drugs or procedures produce similar outcomes, decision makers using a CMA would tally the costs associated with each intervention, and then select the least costly alternative (Robinson 1993a). A CMA is commonly employed to evaluate traditional drugs where many exist in a class, such as statins.

Though it may be better suited for use with traditional medications, a CMA has some limited applications to biologics. A CMA comparing two tumor necrosis factor-alpha (TNF-α) blockers for the treatment of RA, for instance, might include such considerations as:

- How are these agents administered? From an economic standpoint, MCOs favor self-injectables over subcutaneous delivery by physicians (Baker 2005).
- What are the dosing requirements and the potential for having to increase the dosage over time?

Cost-benefit analysis (CBA). A CBA weighs the monetary costs of a course of action against the expected monetary benefits (Robinson 1993b). Such benefits include the medical costs that would have been incurred without the intervention, the monetary value of productivity that would have been lost to illness or death, and even the monetary value of the satisfaction (utility) that would have
Magnitude of chronic conditions

In 2004, per capita health spending among adults age 65 and older was $8,647, compared with $4,647 for persons age 45 to 64, $2,277 for those age 25 to 44, and less than $1,300 for persons younger than 24 (Zuvekas 2007). The uneven distribution of health care spending reflects, in part, the fact that older adults tend to experience more illness and chronic conditions than younger people. It also may reflect the long-standing practice to provide acute treatment once disease has emerged instead of taking steps to prevent it in the first place. Because any savings from preventive care often are slowly realized and difficult to demonstrate, immediate efforts to curtail health care spending have hinged on identifying the small minority of patients who consume a grossly disproportionate amount of health care resources. These patients commonly have chronic conditions, such as heart failure, diabetes, or chronic obstructive pulmonary disease.

Chronic conditions* are found in about 133 million Americans and were projected to affect 157 million by 2020 and 171 million by 2030 (Anderson 2004). Patients with chronic conditions account for 83 percent of U.S. health care spending (Figure 4). Such patients account for 81 percent of inpatient stays, 91 percent of prescriptions, 76 percent of physician visits, and 98 percent of home care visits. If the patient has an activity limitation on top of a chronic condition, resource utilization increases substantially compared with patients who have chronic conditions but no activity limitations.

As of 2001, 25 percent of Americans of any age (but 67 percent of those age 65+) had two or more chronic conditions; 3 percent had five or more. That top 3 percent accounted for 16 percent of total health care spending.

In 2003, the cost of lost productivity to U.S. businesses for the top seven common chronic diseases exceeded $1 trillion (Figure 5). The majority of the lost productivity (80 percent) was attributed to presenteeism (diminished on-the-job productivity), with lost workdays accounting for the other 20 percent. Most of the lost productivity (91 percent) was associated with illnesses, but 9 percent was attributed to employees’ duties as caregivers.

* Illnesses and impairments expected to last at least 1 year, limit a person’s ability to function, and require ongoing medical care.

**FIGURE 4** Health spending is concentrated in people with multiple chronic conditions

83 percent of health care expenditures are for people with one or more chronic illness

<table>
<thead>
<tr>
<th>% of health care spending</th>
<th>Number of chronic conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>17</td>
<td>None</td>
</tr>
<tr>
<td>21</td>
<td>1</td>
</tr>
<tr>
<td>18</td>
<td>2</td>
</tr>
<tr>
<td>16</td>
<td>3</td>
</tr>
<tr>
<td>12</td>
<td>4</td>
</tr>
<tr>
<td>16</td>
<td>5+</td>
</tr>
</tbody>
</table>

% of population: 52

SOURCE: ANDERSON 2004

**FIGURE 5** As chronic disease patients suffer, so does productivity

Seven chronic conditions cost employers more than $1 trillion in lost productivity annually

<table>
<thead>
<tr>
<th>Illness</th>
<th>Lost productivity ($ billions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>$280</td>
</tr>
<tr>
<td>Cancer</td>
<td>$271</td>
</tr>
<tr>
<td>Mental disorders</td>
<td>$171</td>
</tr>
<tr>
<td>Heart disease</td>
<td>$105</td>
</tr>
<tr>
<td>Diabetes</td>
<td>$105</td>
</tr>
<tr>
<td>Pulmonary disease</td>
<td>$94</td>
</tr>
<tr>
<td>Stroke</td>
<td>$22</td>
</tr>
</tbody>
</table>

SOURCE: DEVOL 2007
been lost because of illness or death (Santerre 2004). A CBA is expressed in terms of a cost-benefit ratio.

Studies of the economic benefits of vaccines provide compelling examples of the value of a CBA. In 1969, Axnick published the first CBA of the measles vaccine, which was licensed in 1963. Nationally, the cost of administering the vaccine from 1963 to 1968 was estimated at $108 million. Axnick calculated the economic benefits — hospital days saved, absences from work and school avoided, cases of retardation averted — over the same period at $531 million, for a net savings of $423 million. The cost-benefit ratio is 4.92, meaning every $1 spent on immunization produced $4.92 in benefits (Axnick 1969).

Estimating medical costs is relatively straightforward, but tallying indirect costs complicates a CBA. Quantifying lost productivity requires making projections of a person’s income. Quantifying satisfaction from improved health involves calculating how much a person is willing to pay to achieve a reduction in the probability of being disabled or dying — a soft science that hinges on emotional matters and quality-of-life considerations.

**Cost-effectiveness analysis (CEA).** A CEA is used when different interventions are not expected to produce similar outcomes, so that the costs and effectiveness of each can be considered (Robinson 1993c). For instance, a CEA comparing a TNF-α blocker for plaque psoriasis with a regimen of methotrexate and calcipotriene might consider the additional costs associated with:

- Periodic monitoring of liver function, usually required of patients taking methotrexate because of its toxicity
- Ancillary drugs that may be required with a biologic or nonbiologic regimen

The outcome of a CEA is expressed as dollars per natural unit, such as reductions in mm/Hg of blood pressure reduction or mg/dL of LDL cholesterol.

If the cost and effectiveness of an intervention are uncertain, it can be evaluated by using a risk-averse strategy. A risk-averse strategy constructs a model so that the assumptions are loaded against the new intervention and in favor of the established one. If the new intervention prevails, it is reasonable to assume it is cost-effective.

It has been recommended that cost-effectiveness models be a component of clinical trials, but this would be of little use to purchasers of health care. Such a model could overstate the cost-effectiveness of treatment, because clinical trials are performed under controlled conditions and do not always reflect real-world experience with a therapeutic product.

**Cost-utility analysis (CUA).** A CUA, which is a subset of a CEA, commonly uses the quality-adjusted life-year (QALY) metric to assess the effects of an intervention. A QALY takes into account not just the amount of life gained, if any, but also the quality of the extra time. This sort of analysis can be useful for some oncologic drugs that extend life by a few months or a year. The QALY, however, is controversial in managed care; decision makers do not like it because quality-of-life assumptions may or may not be relevant to a patient’s situation (Hatoum 2004). The QALY is of little value to human resources personnel and chief financial officers, to whom the context of the metric often is not meaningful.

**Cost-consequences analysis (CCA).** A relatively new form of analysis, a CCA provides multiple outcomes (Detsky 1994, 2007; Mauskopf 1998). Decision
A cost-consequences analysis (CCA) generates multiple outcomes and indicates budgetary effects outside the pharmacy benefit.

makers may prefer the CCA, because it overcomes some of the problems associated with CUAs, in particular QALYs and the presentation of benefits as an aggregate (Drummond 2003). Instead of aggregating costs and benefits into QALYs or some other single measure, numerous outcomes are presented, such as direct and indirect costs, effects on quality of life, and clinical outcomes. An advantage of this approach is that it can show how an increase in spending on, for example, biologics, can result in decreased spending in other areas, such as hospitalization or emergency department services.

Data used to construct a CCA are derived from numerous sources, such as clinical trials, epidemiological studies, employment statistics, administrative and health claims databases, patient surveys, and computerized medical records.

Making use of economic data

In 2000, the Academy of Managed Care pharmacy issued the Format for Formulary Submissions, a set of guidelines for manufacturers to follow when including cost-effectiveness projections in product dossiers. AMCP encouraged

<table>
<thead>
<tr>
<th>TABLE Types of economic analyses for making value judgments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<tr>
<td><strong>Use</strong></td>
</tr>
<tr>
<td>Cost-minimization analysis (CMA)</td>
</tr>
<tr>
<td>Identifies the least costly of two or more interventions whose outcomes are regarded as similar</td>
</tr>
<tr>
<td>Cost-benefit analysis (CBA)</td>
</tr>
<tr>
<td>Compares monetary benefits with monetary costs associated with an intervention</td>
</tr>
<tr>
<td>Cost-effectiveness analysis (CEA)</td>
</tr>
<tr>
<td>Compares the costs and benefits of interventions whose outcomes are regarded as dissimilar</td>
</tr>
<tr>
<td>Cost-utility analysis (CUA)</td>
</tr>
<tr>
<td>Same as CEA (CUA is a subset of CEA)</td>
</tr>
<tr>
<td>Cost-consequence analysis (CCA)</td>
</tr>
<tr>
<td>Comprehensively assesses the costs and consequences of an intervention</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Outcome</strong></td>
</tr>
<tr>
<td>Cost-minimization analysis (CMA)</td>
</tr>
<tr>
<td>Dollars per intervention</td>
</tr>
<tr>
<td>Cost-benefit analysis (CBA)</td>
</tr>
<tr>
<td>Dollars associated with direct and indirect costs and benefits</td>
</tr>
<tr>
<td>Cost-effectiveness analysis (CEA)</td>
</tr>
<tr>
<td>Dollars per measureable unit (e.g., percentage - point reduction in HbA1c in diabetic patients)</td>
</tr>
<tr>
<td>Cost-utility analysis (CUA)</td>
</tr>
<tr>
<td>Dollars per quality-adjusted life-year (QALY)</td>
</tr>
<tr>
<td>Cost-consequence analysis (CCA)</td>
</tr>
<tr>
<td>Multiple outcomes</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Strengths</strong></td>
</tr>
<tr>
<td>Cost-minimization analysis (CMA)</td>
</tr>
<tr>
<td>Simple to perform</td>
</tr>
<tr>
<td>Cost-benefit analysis (CBA)</td>
</tr>
<tr>
<td>Considered the most comprehensive form of economic evaluation</td>
</tr>
<tr>
<td>Cost-effectiveness analysis (CEA)</td>
</tr>
<tr>
<td>Outcome is easily understood by clinicians and decision makers</td>
</tr>
<tr>
<td>Cost-utility analysis (CUA)</td>
</tr>
<tr>
<td>Facilitates comparison of disparate programs</td>
</tr>
<tr>
<td>Cost-consequence analysis (CCA)</td>
</tr>
<tr>
<td>Simple, disaggregated format</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Weaknesses</strong></td>
</tr>
<tr>
<td>Cost-minimization analysis (CMA)</td>
</tr>
<tr>
<td>May be too simple to provide meaningful results</td>
</tr>
<tr>
<td>Cost-benefit analysis (CBA)</td>
</tr>
<tr>
<td>Difficult to assign monetary value to indirect costs and benefits; outcome is an aggregate measure</td>
</tr>
<tr>
<td>Cost-effectiveness analysis (CEA)</td>
</tr>
<tr>
<td>Extrapolating data from randomized, controlled trials to construct the model may overstate the effectiveness of an intervention</td>
</tr>
<tr>
<td>Cost-utility analysis (CUA)</td>
</tr>
<tr>
<td>QALY is difficult to understand; measurement of patient satisfaction varies depending on methodology and is subject to debate</td>
</tr>
<tr>
<td>Cost-consequence analysis (CCA)</td>
</tr>
<tr>
<td>Not all data are of comparable quality</td>
</tr>
</tbody>
</table>

health plans to use this information as part of the formulary decision-making process. A dossier is only as useful as the information it contains, however, and health plans and employers commonly contend that the data they need to make meaningful economic projections, such as head-to-head comparisons, are missing from AMCP-style dossiers.

A recent survey of randomly selected MCO representatives sheds light on how the AMCP format is viewed from a payer perspective (Nichol 2007). In the 6 months prior to the study, the 20 MCOs interviewed received 103 drug dossiers prepared by manufacturers; 54 percent of these dossiers received contained budget-impact models, and 39 percent contained cost-effectiveness or cost-benefit analyses. Although some of the MCOs said they include such dossiers in their decision-making processes, others said they don’t use them, largely due to the perception of manufacturer bias.

Most of the MCOs said they modified the economic models they received to make them more applicable to their own populations, but many of the respondents found the models difficult to work with and lacking in technical detail. The qualities that MCOs desire in a model — simplicity, transparency, and ability to be customized — were perceived to be lacking in most cases.

The ability of an MCO to evaluate and use cost-effectiveness evaluations will vary from organization to organization. To help support payers and purchasers in making coverage decisions, the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) is working to standardize approaches to valuation of a health care intervention. ISPOR has called attention to the need to assemble “real-world data” — data collected outside conventional clinical trials (Garrison 2007). Randomized, controlled trials (RCTs) generate results that cannot be applied to general populations, are conducted over relatively short periods, and involve relatively few patients. In short, they may not identify benefits or adverse effects that emerge only after a drug has entered into widespread use.

In the drug-approval process, RCTs enroll patients on the basis of strict inclusion and exclusion criteria. But once a drug is on the market, it is prescribed for many patients whose demographic and clinical characteristics may be considerably different than those enrolled in the trial. Real-world patients may be older, sicker, or less compliant with therapy and, therefore, are unlikely to achieve the same results seen in the RCT.

An ISPOR task force representing academia, pharmaceutical manufacturers, and health insurers has acknowledged that although RCT data have their place, once a drug has been put on the market — and physicians are free to prescribe it as they see fit — RCTs rapidly lose any real-world relevance (Garrison 2007). A problem with real-world data, however, is that they often lack the methodological rigor that characterizes an RCT. The task force is developing methodological guidance for data collection so that real-word studies are useful to payers and purchasers. Such studies, if conducted well, can shed light on a drug’s effectiveness in different practice settings and in diverse patient populations, how a new drug compares with alternative therapies (as opposed to placebo), long-term risks and benefits, dosing strategies, and adherence to therapy (Garrison 2007).

A separate ISPOR task force of employers and insurers also recommends the adoption of various reporting requirements to improve the usefulness of pharmacoeconomic studies to benefits purchasers (Drummond 2003). These requirements include:

Employers and payers need real-world data to make value judgments and coverage decisions.
A sensitivity analysis deals with uncertainty by assigning a value to key variables. In one form of sensitivity analysis, extreme scenarios are constructed, allowing options to be compared under assumptions of high cost and low effectiveness or low cost and high effectiveness.

A working group of employers and insurers is addressing the use of pharmacoeconomic data so they are meaningful to decision makers.

Some biologic therapies compare favorably with conventional drugs but are more expensive. It is vital to determine who benefits from their use.

Some biologic therapies compare favorably with conventional drugs but are more expensive. It is vital to determine who benefits from their use.

Biologics and RA: Example of value

RA is a chronic inflammatory disease that carries enormous costs in terms of decreased life expectancy (Wolfe 1994), increased morbidity and mortality from heart disease (del Rincon 2001), and work-related physical disability (McNeil 1993). It affects about 1 percent of adults, most during their working years, and is more likely to be found in women than in men. Until recently, the majority of patients with RA was thought to have a good prognosis and would respond well to conservative treatments. It also was thought that many of the adverse effects of those treatments were worse than the effects of untreated disease (Pincus 1993).

Now that the natural history of RA is better understood and more effective treatments are available, the goal of treatment is to achieve remission of RA at an early stage to prevent long-term structural damage and disability. As their name implies, disease-modifying antirheumatic drugs (DMARDs) are used to stabilize RA. DMARDs, such as methotrexate or cyclosporine, alter the course of the disease, in contrast to nonsteroidal anti-inflammatory drugs, such as ibuprofen and naproxen, that temporarily relieve symptoms without affecting the underlying disease process. These older DMARDs, however, have toxic profiles that force patients to “rotate” therapies after a period of time.

Several biologic DMARDs that treat RA work by preventing TNF-α, a protein involved in systemic inflammation, from interacting with receptors on neighboring cells. These agents have altered the treatment of RA because they are highly efficacious and appear to have fewer side effects than older DMARDs (Flood 2007). They also are expensive in comparison. The cost differential raises the question: When is it appropriate to initiate treatment with a biologic?

Why RA is important to employers

RA is of direct interest to employers because the disease is common, often emerges during middle age, and can reduce a person’s physical, emotional, and social functioning, even in the early stages of the disease. Studies from the early 1980s show that among workers who were younger than 65 and employed at the time of disease onset, at least 50 percent experienced work disability within 10 years (Pincus 1993). In a study of patients with early-stage RA, treatment with conventional DMARDs was insufficient to prevent one third from losing their employment within 10 years because of health-related reasons (Young 2002).

A more recent investigation — coinciding with the emergence of biologics to treat RA and involving more than 8,000 participants in the National Data Bank for Rheumatic Diseases — suggests that the rate of disability may have decreased somewhat since these earlier studies. These patients were employed at the time of disease onset, and 12 years later, 56.2 percent were still working (Wolfe 2007).

When the disease makes it impossible for employees to execute their duties at
work, they may experience prolonged absence and become eligible for disability entitlements. If an employee with RA is irreplaceable, the employer may be motivated to prevent or mitigate the loss, as the loss of productivity and the cost of training a replacement worker may outweigh the cost of providing the medication in the first place (IBI 2007).

**Considerations in assessing value of RA treatment**

Disability in RA patients results primarily from the progressive destruction of bone in joints, most often detected via radiographs. Apparently caused by inflammation that isn’t apparent during a clinical examination, such structural deterioration can occur even when clinical remission seems to have been achieved with conventional DMARDs. Studies have shown that a TNF-α blocker is superior to methotrexate monotherapy for achieving rapid clinical control of early RA, as well as preventing radiographic structural damage (Ikeda 2007). It remains to be determined whether early prevention of radiographic damage translates into economic benefit.

Another factor that contributes to disability in RA is comorbidity — any condition that exists along with the RA. The average patient with established RA has at least two comorbidities (Michaud 2007). Some comorbidities are a direct result of the RA (e.g., myocardial infarction [MI]); some, such as risk of stroke or osteoporosis, are a consequence of a common risk factor (e.g., smoking); some are treatment related (e.g., risk of infection); and some have no relationship to RA or its treatment. Depression, for example, is a comorbidity associated with many chronic diseases, including RA. Regardless of cause, as the number of comorbidities increases, the level of an RA patient’s functional ability decreases.

It has been argued that initiating biologic treatment of RA at an early stage might reduce direct and indirect costs over time.
RA patients tend to have other serious health problems. This increases employer costs and decreases workers’ functional ability.

Most health care consumption is by patients with chronic conditions. Seven chronic conditions cost employers more than $1 trillion per year.

New biologics are likely to address relatively common chronic conditions. It is important to know how to evaluate these new therapies.

The perspective from which treatment of RA is viewed is critical when comorbidities are being weighed, as the importance of each comorbidity depends on the outcome of interest (Michaud 2007). If work disability is the issue, then, according to an analysis of national registry data, the three most important comorbidities in ranked order are depression, diabetes, and pulmonary disorders. If the outcome is mortality, they are pulmonary disorders, MI, and fracture. And if the outcome is medical costs, the three most important comorbidities are pulmonary disorders, liver disorders, and diabetes.

RCTs are the foundation of evidence-based medicine, but the aforementioned limitations of RCT data complicate evaluations of RA therapies. In the context of work disability, definitions of employed and disabled may vary from study to study, making it difficult to generalize results. Moreover, the relatively short duration of RCTs provide an employer no insight as to whether TNF-α blockade delays the long-term progression of disability, whether it will reduce the risk of costly joint replacement surgery (Kavanaugh 2005), or whether clinical and pharmacoeconomic benefits will persist after a treatment is discontinued (Doan 2006). Though RCTs are essential for initial coverage decisions, assumptions about a product’s effectiveness and cost-effectiveness should be revisited periodically on the basis of experience with it (see “Efficacy vs. Effectiveness,” previous page).

BFAC: OUR ANALYSIS

Biologics raise the stakes in the value equation simply because their prices command attention. Over the next few years, spending on biologics is expected to increase only modestly, but over the longer term, biologics could claim a substantially greater share of pharmacy budgets. Increased utilization would be driven by additional indications for biologics already on the market along with FDA approval of new agents, especially those aimed at relatively common chronic conditions.

Patients with chronic conditions account for 83 percent of U.S. health care spending, and the cost of lost productivity to U.S. businesses from the top seven common chronic diseases exceeds $1 trillion. Purchasers are beginning to understand the magnitude of chronic conditions and the share of health care resources they consume. As purchasers make decisions about coverage for high-cost therapies with an eye toward containing those costs, they need to be cognizant of the effects of those decisions on productivity and on health care utilization outside the pharmacy silo.

Determining the value of a drug is inherently subjective, because different people look at the same drug from different perspectives. In some instances, various stakeholders — patients, employers, physicians, insurers, pharmacy directors, pharmaceutical companies — may agree on the value of a drug, but often they will not. Groups looking at the “value equation” from different perspectives need to know what do with information generated by economic analyses if they are to apply that information in a meaningful way. This chapter provides an explanation of five types of economic analyses for making value judgments. Some analyses are more useful than others. A CMA, for example, offers little or no insight as to the question of value. At the other extreme, a CCA may be much more useful, but also it is much more complicated and requires the compilation of data that may be hard to obtain.

The chief problem facing decision makers who turn to economic models for
guidance about the value of biologics is the quality and suitability of the data upon which those models are built. For lack of anything better, economic analysts tend to rely on RCTs for much of their data. But RCTs are inherently flawed for this purpose. They are conducted in a highly artificial environment in which the inclusion and exclusion criteria create a patient population that probably does not resemble the real-world patient population in which the drug is actually used. Many RCTs, especially those used to gain FDA approval, simply compare a drug against placebo. Purchasers have a very different interest: They want to know how a new drug stands up against existing therapies, not just placebo. They also want to know how a drug performs over the long term, not just over the relatively short intervals studied in RCTs.

By virtue of their combined purchasing power, large purchasers ought to be able to influence manufacturers to generate meaningful data from clinical trials. In the course of these trials, manufacturers also should be encouraged to collect data that shed light on their effects on productivity, especially for drugs that are likely to see substantial utilization in an employee population. Purchasers also can encourage the creation and maintenance of patient registries that generate longitudinal real-world data once a drug is on the market. If manufacturers want purchasers, physicians, and patients to accept the proposition that biologics provide value — that they are worth the investment — then manufacturers have a responsibility to provide decision makers with solid supporting evidence.

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Doan QV, Chiou CF, Dubois RW. Review of eight pharmacoeconomic studies of the value of biologic DMARDs (adalimumab, etanercept, and infliximab) in the management of rheumatoid arthritis. J Manag Care Pharm. 2006;12:555–569.


Affordability and Access

As more biologics enter the market, health plans and employers face the challenge of controlling costs while ensuring that biologics are affordable. This chapter discusses tools and techniques commonly employed to control access to biologics, and examines alternative benefit designs that may improve the affordability and accessibility of biologics for patients who need them.

The country is ambivalent concerning the role for cost in insurance coverage policy, and Medicare is explicitly prohibited from using cost-effectiveness analysis. 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.

— JAMES C. ROBINSON, PhD, Health Affairs, 2006

The Centers for Medicare & Medicaid Services estimates that in 2006, prescription drugs accounted for 10 percent of U.S. health care spending — substantially less than the percentage devoted to hospital care (31 percent) or physician services (21 percent) (Catlin 2008). Still, in the $2 trillion health care sector, that amounted to $217 billion spent on pharmaceuticals. Specialty pharmaceuticals (biologics and high-priced small-molecule drugs) are thought to account for 10 to 20 percent of purchases under the pharmacy benefit (Medco 2007, Express Scripts 2007).

Only a small minority of a health plan’s members — 1 to 5 percent — uses specialty drugs (Goldman 2006), but a single occurrence can be costly. Consider the per-patient per-year costs incurred in 2005 for several biologic therapies by Kaiser Permanente, a large California-based integrated health plan (Table 1).

For a multimillion-member payer, where risk is spread across a large population, expenditures for high-cost, low-incidence-of-use therapeutics are more easily absorbed than in smaller health plans. Express Scripts, a 50 million-member pharmacy benefit manager (PBM), reports that among its commercial clients in 2006, per-member per-year spending for the top three therapeutic categories requiring treatment with a biologic drug (inflammatory conditions, multiple sclerosis [MS], cancer), combined, was $43.08 (Express Scripts 2007). Combined PMPY spending for the top three therapeutic categories treated with nonspecialty drugs (hyperlipidemia, gastrointestinal disorders, mood disorders) was more

| TABLE 1 | Specialty drug costs reported by a large, commercial-sector health plan |
| Costs for indications listed are for calendar year 2005 |
| Trastuzumab (Herceptin): $36,000 for the treatment of breast cancer (6 months of treatment) |
| Rituximab (Rituxan): Up to $32,500 for non-Hodgkin’s lymphoma (8 weeks) |
| Bevacizumab (Avastin) or cetuximab (Erbitux): Up to $28,500 for metastatic colorectal cancer (8 weeks) |
| Etanercept (Enbrel), infliximab (Remicade), anakinra (Kineret), or adalimumab (Humira): $18,000 or more for rheumatoid arthritis |
| Etanercept, efalizumab (Raptiva), or alefacept (Amevive): Up to $22,000 for psoriasis |
| Infliximab: $16,500 or more for Crohn’s disease |

SOURCE: MONROE 2006

Biologic therapies account for 1 to 2 percent of total health care expenditures.
than 4 times that — $199.43. Note that only one half of 1 percent of Express Scripts’ members required a prescription for a biologic therapy to treat one or more of the specialty class conditions. By contrast, the top three nonspecialty classes treat highly prevalent conditions; in 2006, 31 percent of Express Scripts members had one or more prescriptions in one or more of these classes.

Of the 12 top-selling biologic products (Figure 1), most are used in oncology, either as direct therapy for malignancies or as supportive therapy. Treatment of autoimmune disorders (such as rheumatoid arthritis [RA], Crohn’s disease, psoriasis) is the chief use for most of the other top sellers. The universe of people who use specialty drugs is expected to increase as products serving larger populations come to market. For example, biologics for the treatment of osteoporosis (denosumab) and diabetes (a once-weekly version of exenatide) are in late-stage development. As these gain approval and as those biologics already approved secure additional indications, health plans and employers utilize benefit designs that limit the use of these powerful but costly products to only the most needful patients. They also face the challenge of trying to ensure that biologics are affordable and accessible to patients who can benefit from them.

**Benefit design issues**

Most health plans adjudicate drug benefits in two ways. Conventional outpatient drugs are covered under the pharmacy benefit, which increasingly extends to self-administered biologics. With a drug that is covered under the pharmacy benefit, a physician writes the prescription, which the patient takes to a retail pharmacy or obtains through a specialty pharmacy. Biologics that must be infused or injected intramuscularly, however, are treated differently; the physician not only prescribes the product but also administers it, primarily because of safety concerns and the skill level required for administration. The health plan is
billed under the member’s medical benefit for an amount that allows the physi-
cian to recover the cost of the product plus a markup to cover overhead costs.

Known as buy and bill, this business practice generates a considerable amount
of revenue for physicians. Buy and bill gives physicians a financial incentive to
favor a product that requires professional administration over one that can be
injected by the patient at home. In part to counter this practice (among other rea-
sons), health plans seek to move biologics, where possible, to the pharmacy ben-
efit side, where utilization and cost-containment tools can be applied.

The maintenance of separate pharmacy and medical benefits in a plan design
may create problems of a different kind, however. Managers of the pharmacy
benefit may be unaware of the potentially positive effects of increased pharmacy
spending on medical spending, such as a reduction in ER visits or hospitaliza-
tions. These benefits may be realized over the long term in many instances and,
thus, may be difficult to reconcile with short-term financial objectives.

Some MCOs have begun to address this problem by constructing an over-
arching benefits framework that establishes continuity between medical and
pharmacy benefits and allows therapeutic decisions to be based on considera-
tions of clinical effectiveness and cost-effectiveness (Watkins 2006). Coordinating med-
ical and pharmacy benefits allows a health plan to establish a treatment algorithm
requiring that a product covered under the pharmacy benefit be tried before a
drug covered under the medical benefit is used. For such a plan to be successful,
health plans and employers, which often carve out management of their phar-
macy benefit to a PBM, should align objectives and collaborate with the PBM.

Tools for restricting access

The same tools that have been employed to manage conventional drugs are
used for biologics and other specialty pharmaceuticals. These include:

- Prior authorization, which establishes criteria that must be met prospec-
tively before coverage will be granted for a pharmaceutical product
- Formulary management, which employs financial incentives and disincent-
tives to drive utilization of certain drugs while discouraging use of others
- Utilization review, which verifies the medical necessity of a treatment
- Claims review, a retrospective examination of whether drugs are used in ap-
propriate dosages
- Evidence-based guidelines, which establish a standard of care based on cli-
nical trial or real-world outcomes
- Case management, which is similar to disease management but involves in-
dividualized care programs for patients who need specialty therapeutics

Prior authorization is one of the most common tools employed to limit the
supply of health care. Formulary management, which includes the use of co-
payments and coinsurance, is intended to control utilization from the demand
side, either for clinical or financial reasons, or both. The use of prior authoriza-
tion and formulary management presents issues of access and affordability, and
raises questions about where the “tipping point” lies between appropriate uti-
lization control and arbitrary rationing that may have deleterious effects on a
member’s health and a payer’s total health care costs for that member.

Prior authorization. Prior authorization establishes a process that must be

Most biologics are covered under the medical benefit. The pharmacy benefit offers more transparency of drug costs.

An integrated benefit design may give a more full picture of health care costs and cost offsets that could result from biologic use.

The most common techniques for controlling access to biologics are prior authorization and cost sharing.
Coinsurance and copayments are common cost-sharing tools. Biologics most likely to require cost sharing are those that treat RA, psoriasis, and multiple sclerosis.

Criteria for prior authorization differ from disease to disease and even from medication to medication.

Cost sharing. The most common cost-sharing arrangements are copayments (a fixed sum that a patient pays to receive a drug regardless of its cost) and coinsurance (a percentage of the drug’s price borne by the patient). Occasionally, some drugs entail both a copayment and coinsurance. Cost sharing may be a feature of the pharmacy benefit or the medical benefit, or a drug may be carved out of the normal benefit structure and its management assigned to a specialty pharmacy, which may apply its own cost-sharing mechanism.

In The Zitter Group survey, the therapeutic categories of injectable or infused pharmaceuticals most likely to require some form of cost sharing were RA, psoriasis, and MS, while those least likely to incur cost sharing were IV immune globulin, IV oncology, and hemostatics (Zitter 2007). When copayments are required, the patient’s contribution usually is relatively minimal: The average copayment for an injectable product is $45 (Table 2, page 32).² When coinsurance is required, however, the average rate of 23 percent can skew cost sharing considerably in absolute terms, depending on the price of the medication. A patient with RA whose plan requires 23 percent coinsurance for a TNF-α inhibitor with an average retail cost of $450 per week would incur a $103.50 weekly cost share.

Copayments commonly are used in conjunction with tiered formularies, which are intended to drive utilization of certain products while discouraging followed before a prescribed drug is covered. The physician must document either the need for the proposed treatment or that standard therapies have been tried without success. Diagnosis by a specialist may be required, and treatment may be authorized for a limited length of time, with the added provision that the patient must periodically demonstrate a satisfactory response to treatment.

Criteria for granting prior authorization vary by disease, depending upon the rationale used. Robinson (2006) has reported the prior authorization requirements at Blue Shield of California for biologic utilization in RA, psoriasis, and allergic asthma. In recognition of the potential severity of RA, the only requirements at the time were that the disease be diagnosed by a rheumatologist, that the patient fail to respond adequately to methotrexate or another disease-modifying anti-rheumatic drug (DMARD), and that the patient be reevaluated after 12 weeks. For psoriasis, where the concern is that biologics may be inappropriately prescribed for mild disease, prior authorization requirements extended to diagnosis by a dermatologist or rheumatologist; age of 18 or older, in keeping with labeling at the time; the presence of moderate to severe disease for at least 1 year over a significant amount of body surface; inadequate response to ultraviolet treatment and DMARDs; and a reevaluation after 12 weeks. In allergic asthma, the insurer’s concern was that omalizumab (Xolair) be reserved generally for patients whose asthma, historically, has been difficult to control with other agents. Blue Shield of California required that, in accordance with the drug’s label, omalizumab not be used in patients with mild disease or used for prevention, as well as evidence that conventional treatments have been tried. Initially, about half the requests Blue Shield of California received for omalizumab were denied because it was sought for off-label use or for patients who hadn’t tried standard therapies, but denials later had become rare because most requests conformed to the approved use. The condition being treated also affects the extent to which prior authorization is enforced. In a national survey of managed care decision makers, The Zitter Group determined that rates of “aggressive enforcement”¹ ranged from 9 percent for intravenous (IV) cancer therapies to 75 percent for growth hormone (Figure 2).

The most common cost-sharing arrangements are copayments (a fixed sum that a patient pays to receive a drug regardless of its cost) and coinsurance (a percentage of the drug’s price borne by the patient). Occasionally, some drugs entail both a copayment and coinsurance. Cost sharing may be a feature of the pharmacy benefit or the medical benefit, or a drug may be carved out of the normal benefit structure and its management assigned to a specialty pharmacy, which may apply its own cost-sharing mechanism.

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1 The Zitter Group defines “aggressive enforcement” as step edits locked into the reimbursement system. This is opposed to “moderate enforcement” (where a medical director reviews some cases) or no active enforcement of prior authorization policies.

2 The average copayment for a third-tier drug is $45.12, but jumps to $87.78 for a fourth-tier product.
use of others. A three-tiered formulary is typical, but some formularies contain four, and a few have five or even six tiers. Tiers themselves can be misleading; their use implies the existence within a therapeutic category of several different products that are thought to be essentially equivalent in terms of risks and benefits, and may give the impression that the evidence for or against a drug’s effectiveness determines its tier placement. Neither of these inferences is true. Once a drug is deemed safe and effective and is added to a formulary, its tier placement is most often a matter of its acquisition cost or rebates than of its clinical or cost-effectiveness (Kleinke 2004, Dalzell 1999). Moreover, many biologics are unique, lacking comparable drugs in their therapeutic class.

In a survey of pharmacy benefit design experts, tiered copayments were considered to be ill suited for biologics (Malkin 2004). Given the cost of biologics, coinsurance was the cost-containment tool most likely to be used by payers, followed by moving drugs from the medical to the pharmacy benefit where possible.

**Effects of cost sharing on patients**

About 30 percent of MCOs require cost sharing for specialty pharmaceuticals administered intravenously by oncologists — bevacizumab (Avastin), cetuximab (Erbitux), and other IV cancer therapies.

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**FIGURE 2** Prior authorization rigor by therapeutic area

*In a survey by The Zitter Group, 99 MCO decision makers indicated the level of enforcement of internal prior authorization policies for that agent*

<table>
<thead>
<tr>
<th>Therapeutic Area</th>
<th>Aggressive enforcement</th>
<th>Moderate enforcement</th>
<th>Not actively enforced</th>
<th>No PA guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human growth hormones</td>
<td>74.7%</td>
<td>20.2%</td>
<td>5.1%</td>
<td>0.1%</td>
</tr>
<tr>
<td>Respiratory syncytial virus</td>
<td>55.6%</td>
<td>28.3%</td>
<td>10.1%</td>
<td>6.1%</td>
</tr>
<tr>
<td>Infertility agents</td>
<td>53.5%</td>
<td>24.2%</td>
<td>12.1%</td>
<td>10.1%</td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>53.5%</td>
<td>33.3%</td>
<td>9.1%</td>
<td></td>
</tr>
<tr>
<td>Chronic plaque psoriasis</td>
<td>51.5%</td>
<td>33.3%</td>
<td>10.1%</td>
<td>5.1%</td>
</tr>
<tr>
<td>Severe asthma (IgE-mediated)</td>
<td>48.0%</td>
<td>35.7%</td>
<td>12.2%</td>
<td></td>
</tr>
<tr>
<td>Hepatitis C (PEGylated interferons)</td>
<td>46.5%</td>
<td>34.3%</td>
<td>10.1%</td>
<td>9.1%</td>
</tr>
<tr>
<td>Crohn’s disease</td>
<td>42.9%</td>
<td>38.8%</td>
<td>10.2%</td>
<td>8.2%</td>
</tr>
<tr>
<td>IVIG agents</td>
<td>39.4%</td>
<td>39.4%</td>
<td>12.1%</td>
<td>9.1%</td>
</tr>
<tr>
<td>Red blood cell growth factors (ESAs)</td>
<td>39.4%</td>
<td>36.4%</td>
<td>14.1%</td>
<td>10.1%</td>
</tr>
<tr>
<td>Oral cancer therapies</td>
<td>24.2%</td>
<td>37.4%</td>
<td>21.2%</td>
<td>17.2%</td>
</tr>
<tr>
<td>Multiple sclerosis</td>
<td>23.2%</td>
<td>43.4%</td>
<td>22.2%</td>
<td>11.1%</td>
</tr>
<tr>
<td>Hereditary emphysema</td>
<td>21.4%</td>
<td>24.5%</td>
<td>25.5%</td>
<td>28.6%</td>
</tr>
<tr>
<td>Hemostatics (Factor VIII agents)</td>
<td>21.2%</td>
<td>40.4%</td>
<td>24.2%</td>
<td>14.1%</td>
</tr>
<tr>
<td>White cell growth factors (GCSFs)</td>
<td>20.2%</td>
<td>36.4%</td>
<td>26.3%</td>
<td>17.2%</td>
</tr>
<tr>
<td>IV cancer therapies</td>
<td>9.1%</td>
<td>33.3%</td>
<td>36.4%</td>
<td>21.2%</td>
</tr>
</tbody>
</table>

**Percentage of respondents**

ESA=Erythropoiesis stimulating agent, GCSF=granulocyte cell stimulating factor, IgE=immunoglobulin E, IV=intravenous, IVIG=intravenous immunoglobulin.

**SOURCE:** ZITTER 2007
Erbitux), trastuzumab (Herceptin), and panitumumab (Vectibix) — mostly in the form of coinsurance. The average copayment for most of these oncology products is around $44, and the average rate for coinsurance is about 22 percent (Zitter 2007). Political considerations and the influence of advocacy groups make it unlikely that payers will require high coinsurance rates for cancer therapies (Zitter 2006), although it could be argued that a coinsurance rate of 22 percent on a $36,000 treatment (e.g., a 6-month course of trastuzumab) would impose an amount of coinsurance ($7,920) that would be unaffordable to the average patient. Moreover, a substantial share of health plans do not count prescription drug cost sharing toward a member’s out-of-pocket spending cap (Figures 3A and 3B).

Several studies cited in Chapter 1 documented that, for most health care products and services, copayments tend to have the desired financial effect: Higher copayments reduce utilization. Out-of-pocket expenses become a de facto barrier to access, depending on the value a patient places on that product or service relative to alternatives. But at what point does that begin to affect health outcomes?

The Rand Health Insurance Experiment (discussed in Chapter 1) found that among people whose risk of developing a disease or complications of an existing condition is low, reduced health care consumption seemed to have little or no overall effect on health. For people at higher medical risk, though — especially those in lower income brackets — limiting access to care through higher out-of-pocket outlays had a negative effect on health outcomes (Newhouse 1993). Since then, only a limited number of studies have been conducted to qualify the health consequences of reduced prescription drug use, but a handful of recent published works would seem to confirm the HIE’s initial finding. Heisler (2004) examined “cost-related prescription drug underuse” to show that health is worse among those who report such underuse. Chandra (2006) found that, among patients with chronic conditions, increases in prescription drug copayments correlate with a significant rise in hospital admissions as drug use falls. Examining these findings in the context of the HIE, Gruber (2006) offered that access limitations resulting from high cost sharing “suggest the value of considering targeted coinsurance approaches that minimize costs” to lower-income individuals.

Various benefit designs seem to have had a less dramatic impact on the utilization of biologics. Goldman (2006) looked at this phenomenon in more detail and found that although cost sharing may be effective for reducing the utilization

### TABLE 2

**Average copayments and coinsurance for biologics**

*Per prescription, fall 2007, based on a survey of 100 MCOs*

<table>
<thead>
<tr>
<th>Therapeutic category</th>
<th>Copayment ($)</th>
<th>Coinsurance (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biologic response modifier (e.g., biologic DMARDs for RA)</td>
<td>45.85</td>
<td>23.0</td>
</tr>
<tr>
<td>Erythropoiesis stimulating agents</td>
<td>45.05</td>
<td>23.0</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>41.96</td>
<td>24.9</td>
</tr>
<tr>
<td>Human growth hormone</td>
<td>46.27</td>
<td>25.9</td>
</tr>
<tr>
<td>Multiple sclerosis</td>
<td>45.24</td>
<td>23.7</td>
</tr>
</tbody>
</table>

DMARD = disease-modifying antirheumatic drug, RA = rheumatoid arthritis.

*SOURCE: ZITTER 2007*
of traditional pharmaceuticals — doubling the coinsurance rate reduces utilization by about 30 to 50 percent — specialty pharmaceutical use is relatively immune to cost sharing. An analysis of claims data showed that doubling the coinsurance rate reduced the use of specialty drugs for RA by 21 percent; kidney disease, 11 percent; MS, 7 percent; and cancer, 1 percent. Goldman concludes:

When patients derive great benefit from a specialty drug [and] demand is inelastic, high cost sharing is undesirable. … Given the high cost of these specialty drugs, insurers would be better off finding ways to manage utilization so only patients who would benefit will get access to them, rather than pursuing high copayment policies designed to deter use by all patients regardless of clinical need. … Management of [specialty products] may rightly focus on making sure that only patients who will most benefit receive them, but once such patients are identified, it makes little sense to limit coverage.

Goldman’s findings could be interpreted to say that traditional cost-cutting mechanisms are counterintuitive when applied to drugs for which patients perceive a strong need. This would suggest that the patients with chronic or life-threatening conditions place a high value on therapies that they believe could improve health, quality of life, or both.

Improving benefit design: examples and a case study

If traditional cost sharing is ineffective and even inappropriate for biologics, is there a better way to construct formularies? Beginning in 1998 with Regence BlueShield, in Seattle, some U.S. insurers have turned to value-based evidence guidelines to inform their formulary decisions (Neumann 2004). Requiring drug

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**FIGURE 3A**

Distribution of out-of-pocket maximums, 2007

Among all types of benefit plans,* percentage of enrollees whose maximums are shown below:

<table>
<thead>
<tr>
<th>Annual maximum</th>
<th>Single coverage</th>
<th>Family coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;$1,000</td>
<td>7%</td>
<td>10%†</td>
</tr>
<tr>
<td>$1,000–$1,999</td>
<td>44%</td>
<td></td>
</tr>
<tr>
<td>$2,000–$2,999</td>
<td>27%</td>
<td>15%</td>
</tr>
<tr>
<td>$3,000–$3,999</td>
<td>22%‡</td>
<td>24%</td>
</tr>
<tr>
<td>$4,000–$4,999</td>
<td></td>
<td>15%</td>
</tr>
<tr>
<td>$5,000–$5,000</td>
<td>12%</td>
<td></td>
</tr>
<tr>
<td>$6,000 or more</td>
<td>24%</td>
<td></td>
</tr>
</tbody>
</table>

*Includes high-deductible health plans (HDHPs). By federal law, Health Savings Accounts-qualified HDHPs have an out-of-pocket maximum of $5,500 for individuals and $11,000 for families.
†10% of enrollees with family coverage have an out-of-pocket maximum of under $2,000.
‡22% of enrollees with single coverage have an out-of-pocket maximum of $3,000 or more.

**FIGURE 3B**

Prescription drugs often do not count toward limit

Percentage of workers for whom prescription drug copayments or coinsurance do not count toward annual out-of-pocket limits, by types of benefit plan

<table>
<thead>
<tr>
<th>Benefit plan</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>HMO</td>
<td>61</td>
</tr>
<tr>
<td>PPO</td>
<td>79</td>
</tr>
<tr>
<td>Point-of-service plan</td>
<td>60</td>
</tr>
<tr>
<td>High-deductible health plan</td>
<td>40</td>
</tr>
</tbody>
</table>

SOURCE: KAISER 2007
manufacturers to submit a standardized set of clinical and pharmacoeconomic evidence if they want their products to be considered for formulary inclusion, Regence followed an example set by national authorities in Australia, the United Kingdom, Canada, and the Netherlands, where evidence of cost-effectiveness is a part of formulary decisions. Regence required manufacturers to submit a dossier containing clinical and economic data from published and unpublished studies, along with a pharmacoeconomic projection of the product’s likely effect on health and economic outcomes (Mather 1999). The Academy of Managed Care Pharmacy then used the Regence guidelines as the basis for its own set of guidelines that it issued in 2000 and encouraged health plans to adopt.

The AMCP Format for Formulary Submissions, as it was called, was a first step toward encouraging health plans and employers to consider the combined effect of clinical and financial outcomes in pharmacy benefit design. The following year, Fendrick proposed a “benefit-based” copayment scheme, in which a member’s cost sharing would be based on the potential for clinical benefit. Translated into tiers, this type of plan might offer no copayment for a drug that could save a person’s life, a smaller copayment for products that extend life or improve productivity, and a larger one for products whose clinical value cannot be easily characterized. In touting the benefits of the plan, Fendrick also acknowledged its primary limitation: Substantial time and effort would be required to identify clinical and economic considerations that result in appropriate copayments from person to person (Fendrick 2001).

A handful of health plans and employers have tried this approach, and at least one large employer has documented overall cost savings as a result. Two national commercial payers, Cigna HealthCare and Humana, have adapted Fendrick’s work in what has become known as value-based insurance design. Cigna is developing a four-tier formulary plan it calls a “tiered clinical utility” approach, with “lifesaving” drugs on the lowest-cost tier and “lifestyle” products on the highest (Rosen 2006). In the case of Humana, tiers are called groups: Group A is reserved for products that Humana says demonstrate a positive health outcome within 1 year: Brand and generic drugs for asthma, bacterial infections, juvenile diabetes, depression, HIV, and prevention of pregnancy. Group B is for products that control illness and chronic conditions within a 1–2 year period: Brand and generic drugs for cancer, heart disease, and MS. Group C includes products that might improve daily functioning for people with arthritis, chronic pain, allergies, and other products that might affect their productivity; and Group D products address lifestyle conditions, such as hair loss or erectile dysfunction, or those with long-term consequences, such as obesity or tobacco addiction (Sipkoff 2004). In a cost-sharing twist that encourages compliance, members pay the full cost of the drug on the first prescription, but receive rebates of $5 (for Group D products) to $40 (for Group A products) when refilling their prescriptions.

Similar work, called value-based benefit design, is occurring in the employer sector. Marriott, Eastman Chemical, and the University of Michigan are among a small group of companies following the lead of Pitney Bowes, which in 2000 bought into the notion that chronically ill patients might be able to avoid expensive care if their medications were made available to them at little or no cost. Pitney Bowes’ own claims experience suggested that healthy employees would consume $100 to $700 in health care annually, but an employee diagnosed with diabetes, for instance, would require $10,000 or more in health care. The biggest
risk for this disparity in health care costs, however, was not the presence of a chronic illness, but failure to refill prescriptions. “Our experience has been that people don’t take [a drug] if they can’t afford it,” Pitney Bowes’ benefits manager said in a recent article in *Biotechnology Healthcare* (Carroll 2008).

Pitney Bowes removed cost barriers for prescription drugs it considered to be of high value. Among employees and their dependents with asthma, refill rates improved. The increase in drug expenditures was more than offset by a 20 percent reduction in ER visits. Similar effects were seen with employees with diabetes, among whom ER visits dropped 35 percent. In the first year alone, Pitney Bowes saved $1 million in cost offsets (Sipkoff 2004).

Vogenberg (2007) suggests that employers should take an active interest in benefit design for biotech drugs, and develop their own actuarial models to assess the financial effects of different designs from various perspectives. Some employers using a total cost-of-care model have found that although the treatment of MS with biotech drugs results in higher drug costs, other health care expenditures decline, along with absenteeism costs. Models can be tailored to the employer’s need to reflect the estimated prevalence of the conditions of interest in the covered population and the various costs for those conditions: drugs; medical care; lost productivity owing to presenteeism (i.e., workers who are physically present but whose output is below their usual level); and absenteeism, including costs of sick leave, disability, and workers’ compensation.

**Encouraging greater use of value-based tools**

Value-based benefit design is one of a number of tools available to employers that has the potential to lead to more cost-effective and efficient care. Other value-based health care strategies include greater use of health plan quality data (e.g., National Committee for Quality Assurance accreditation or NCQA’s Health Plan Employer Data and Information Set); pay-for-performance programs; incentives to steer employees to physicians with documented high-quality care; or purchasing initiatives, such as those developed by the Leapfrog Group to encourage best practices in hospitals. Despite the existence of some of these tools for a decade or more, however, employers do not yet seem, to a great degree, to embrace programs in line with value-based ideals (Rosenthal 2007). The questions, then, are: What barriers must employers overcome internally? And, what data or tools do they need to enable access to medically effective and cost-effective treatments?

**BFAC: OUR ANALYSIS**

As a share of total health spending, prescription drug expenditures remain relatively small — 10 cents on the dollar. Biologics account for just 1 to 2 percent of total health spending, but their emergence has introduced a new dimension into the cost equation. Until now, a drug that cost several hundred dollars per month or a few thousand dollars per year was regarded as expensive. For patients with chronic conditions requiring multiple prescriptions, annual drug spending could amount to a substantial, but manageable, sum. With biologics, one month’s treatment can tally thousands of dollars and annual spending can run into six figures.

Most of the increased spend on biologics has resulted from new uses for a handful of existing biopharmaceuticals. The biotech pipeline is flush, however, and projections suggest that beginning in 2010, many more new agents will reach

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3 In later years, Pitney Bowes applied this concept to biologics, picking up all costs after an employee spends $1,000 out of pocket. The company is evaluating the return on this investment.
As biologics treat more conditions, payers will be challenged to create benefit designs that make biologics affordable and accessible.

High cost sharing creates *de facto* inaccessibility that may increase use of other health care resources.

Value-based benefit designs should dovetail with a company’s strategic goals.

the market. This will steepen the upward curve, in terms of the share of drug spending devoted to biologics. This event is no longer in the distant future, and plan sponsors have become acutely aware of it.

Moreover, 55 percent of workers with employer-sponsored health coverage face a lifetime limit on their benefits, and for 23 percent, that limit is under $2 million (Kaiser 2007). Some new therapies can — in short order — consume all or a large part of lifetime limits, which have not kept pace with health care inflation over the decades (Lee 2008, Carreyrou 2007). These developments present formidable problems for patients and health plans in terms of access and affordability, and for plan sponsors, they raise fundamental questions about management and financing of biologics.

What to do about it? In the past, each drug was designed to treat only one condition. Today’s biologics are complex products, and each may carry numerous indications. Traditional formulary designs are not structured to accommodate these types of therapies. Moreover, biologics are powerful products, and, in real-world experience, some are much more effective and tolerable than older agents in patients with hard-to-treat diseases. Old-style step therapy does not translate to biologics; a protocol that prevents patients from getting the right drug the first time runs counter to the promise of personalized medicine.

When applied to high-cost biologics, conventional cost-sharing approaches used in drug benefit designs do not materially reduce costs. It is important to recognize that increasing cost sharing to a level that renders a biologic essentially unaccessible may have the unintended effect of increasing the utilization of other health care resources, such as hospital admissions and ER visits. If patients are inappropriately dissuaded from using effective biologics, employers risk experiencing increases in disability claims and declines in productivity.

A more fruitful approach would be to develop cost-sharing schemes based on the benefits a drug provides. A value-based benefit design would drive patients toward agents with higher value; medications that deliver the highest value would be assigned low (or conceivably no) copayments and coinsurance rates, and drugs that provide lesser value would carry higher cost-sharing responsibilities.

Historically, plan sponsors have refrained from applying benefit-based designs to specialty pharmacy, but in light of the number of biologics in the pipeline, the prudent benefit manager should be developing such a strategy now. This begins with identifying corporate goals and then designing a benefit plan that helps a company to achieve them, as opposed to implementing a health plan that focuses primarily on health benefit cost containment but has no direct relevance to a company’s strategic goals.

Pitney Bowes, for instance, had a simple goal: to maintain a happy, healthy workforce that would contribute to the company’s bottom line. Pitney Bowes managers understood that plan designs that would discourage employees from filling prescriptions would lead to unhappy, unhealthy employees, higher rates of absenteeism and disability, and, ultimately, a reduced bottom line. The proof of the approach taken by Pitney Bowes is reflected in cost savings reported herein.

This task will differ for each employer, depending on its goals, workforce demographics, and past claims experience. Marriott, Caterpillar, and other companies that have developed similar value-based benefit plans have, first, had to analyze their claims data, absenteeism profiles, and profits and ask, “What do these tell us?” The answer will be different from company to company, and so each em-
employer’s benefit-design needs will differ. Benefit managers will want to shop for a managed care partner that is willing to do this hard work with them; cookie-cutter benefit designs will no longer suffice.

Actions and policies that emerge from this work should be grounded in a solid evidence base. There is a need for independently conducted postmarketing studies of the safety, efficacy, and value of biologics to confirm the value of this approach.

References


Medical resources are efficiently used when a given total expenditure cannot be reallocated to alternative kinds of care to achieve an improved medical outcome.

— Henry J. Aaron, PhD, The Challenge of Rationing Health Care, 2005

Achieving efficiency in health care is not simply a matter of achieving improved medical outcomes. In health care, efficiency is multidimensional. Moreover, just what is efficient depends on whose interests are at stake — making any assessment of efficiency in health care complicated when applied to biologics.

Managing biologics effectively requires heeding all the factors that characterize efficiency in health care. In this chapter, we explain those factors in terms of types of efficiency. We pay particular attention to them in the context of mode of administration, a common proxy for efficient management of biologics. Understanding how each type of efficiency affects another can inform drug selection on the basis of mode of administration. In turn, this presents opportunities to keep health care benefits affordable and enable rational access to biologics.

### Types of efficiency

Aaron (2005) has identified five types of efficiency involved in health care resource use: medical, distributional, insurance, dynamic, and production (Table). It should be immediately obvious that full efficiency in health care through the application of all these criteria is elusive. The goal, then, is to achieve efficiency to the fullest extent possible by leveraging each of these types of efficiency to help patients, third-party payers, and employers gain the greatest possible benefit from a health care intervention. Many factors — benefit design and each party’s perspective on the value of biologics, to name two examples previously discussed in this monograph — can affect the degree to which these types of efficiency can be achieved. Approaching full efficiency, then, requires an understanding of how one type of efficiency can affect another. This is especially true when applied to the administration of biologics.

**Medical efficiency.** Simply put, medical efficiency occurs when one health care intervention results in greater clinical benefit than another intervention or by doing nothing at all. For example, a benefit design that allows access to a variety of biologic products can promote medical efficiency, while a design that limits access to certain biologic products on the basis of their mode of administration can, in some instances, run the risk of attenuating medical efficiency.

In cases where a clinician has a choice of two or more biologics that work in similar fashion, some MCOs have begun to designate preferred products. This is
Therapeutic interchange differs from therapeutic substitution, in which one chemically equivalent product replaces another, such as substituting generic simvastatin for Zocor. Because of their complex molecular structure, no two biologic products are alike, and as such, are not therapeutically equivalent.

true for growth hormone, hepatitis C, and multiple sclerosis agents (Carroll 2006). More recently, Medicare Part D plans, state Medicaid agencies, and some commercial payers have begun to designate preferred tumor necrosis factor (TNF)-α inhibitors for the treatment of rheumatoid arthritis (RA) and psoriasis (TennCare 2007, Washington 2007, Aetna 2007, Anthem 2008). With few exceptions, there is today no a priori method for determining whether a biologic is likely to work as intended in a specific patient (Flood 2007). If a patient has reached the point where treatment with a biologic is recommended, then in the absence of contraindications and a test to determine whether that biologic will be effective, it is reasonable for an MCO to require that therapy be initiated with the lowest-cost or preferred product, assuming choices exist within a class.

Many medical and pharmacy directors consider most biologics to be unmanageable, because many are sole products within their class. Where a choice exists, say, between a self-injectable and an infused biologic, the self-injected therapy is usually less expensive to administer than an infused drug, which must be given by a physician or another health care professional. Medically, though, not all patients will respond well to treatment with a self-injectable — a patient may achieve better results if switched to an infused drug, just as a patient who does not show improvement with an infused drug will achieve a better response upon being switched to a self-injected medication (Cohen 2005, van Vollenhoven 2003).

When the condition of a patient already undergoing treatment with a particular biologic has been stabilized, it would not be reasonable to institute therapeutic interchange1 — the practice of switching a patient from one drug to another in its class (e.g., a TNF-α inhibitor) that is similar but chemically distinct — because of the potential for the new biologic to be less effective, ineffective, or harmful (Flood 2007). Requiring a patient who is doing well on one therapy to switch to a newly designated preferred product may result in adverse effects, recurrence of disease, and costly medical care. An ineffective drug cannot be a medically efficient drug. In the face of treatment failure, all efficiencies have been lost.

To achieve medical efficiency, then, it is important to identify the most clinically effective drug for a particular patient and to minimize the factors that would

Achieving medical efficiency requires the ability to have flexibility in therapeutic choices. An ineffective drug cannot be medically efficient.

<table>
<thead>
<tr>
<th>Efficiency type</th>
<th>Objective</th>
<th>Objective is met when…</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical</td>
<td>Devise service mix resulting in greatest possible medical benefit</td>
<td>Every medical service provided produces more benefits per dollar than services not provided</td>
</tr>
<tr>
<td>Distributional</td>
<td>Distribute services so as to satisfy values and preferences</td>
<td>Not achievable in practice — no combination of ethical judgments results in a universally acceptable distribution plan</td>
</tr>
<tr>
<td>Insurance</td>
<td>Protect the insured from risks causing greatest financial disruption</td>
<td>The highest possible welfare is produced for the insured, given total insurance costs</td>
</tr>
<tr>
<td>Dynamic</td>
<td>Provide incentives that promote development of cost-effective technology</td>
<td>Not fully achievable — it is unknown whether a payment system resulting in excess care promotes scientific advances</td>
</tr>
<tr>
<td>Production</td>
<td>Use fewest possible resources to produce a given quantity of health services</td>
<td>No other production method would result in greater total output</td>
</tr>
</tbody>
</table>

SOURCE: AARON 2005

1 Therapeutic interchange differs from therapeutic substitution, in which one chemically equivalent product replaces another, such as substituting generic simvastatin for Zocor. Because of their complex molecular structure, no two biologic products are alike, and as such, are not therapeutically equivalent.
affect the patient’s ability to benefit from it, be they medical, financial, or practical considerations. A primary step toward achieving medical efficiency is through reasonable access to a variety of effective biologic products.

**Distributional efficiency.** As its name implies, distributional efficiency is perhaps most closely associated with a drug’s mode of administration. Within a population, complete distributional efficiency — getting the right drug to the right patient in the right setting, to quote an oft-cited goal — will always be a challenge, however, because it is impossible to allocate limited health care resources in a way that satisfies everyone.

As discussed in Chapter 2, the perspective from which a health care intervention is viewed strongly influences its perceived value. The same is true for perception of cost. A pharmacy budget manager, for instance, might view the cost of a biologic in terms of its market price. A medical director might characterize the cost of a biologic as including its acquisition cost and such considerations as whether it must be administered by a health care professional. A physician could argue that though home infusion may appear to be less costly than an infusion or injection in the physician’s office, medical supervision provides the means for managing an adverse reaction, which ultimately could prove more cost-efficient. An employer might take into consideration whether the total costs associated with a drug are offset by reductions in an employee’s time off work and by gains in productivity. Together, these perspectives can help to identify the optimal way of giving a drug to a patient — the essence of distributional efficiency.

To illustrate the point, consider the assumption that an oral or a self-injected medication, if available, may be more cost-efficient than one that is administered by a health care professional. An MCO may prefer self-administration of a biologic for this reason and because the self-administered product is usually adjudicated under the pharmacy benefit, which gives the MCO or its pharmacy benefit manager considerable flexibility in exercising cost-containment strategies. But an MCO has no guarantee that a self-administered drug is being taken correctly — or at all. A drug that is infused by a health care professional offers a compliance benefit, which has more value than the cost of a drug not taken.

This shows how a focus on one type of efficiency can affect another — in this case, the assumption of a distributional efficiency upsets medical efficiency. The medical efficiency of any health care intervention is nullified if the patient does not adhere to therapy. Patients have poorer health outcomes when they do not take their medications (Osterberg 2005, Horwitz 1993), and 33 percent of hospital admissions result from noncompliance (McDonnell 2002). The many complexities of nonadherence, discussed later in this chapter, apply to biologics and nonbiologics alike.

**Insurance efficiency.** Aaron’s description of this type of efficiency — to protect one from risks that cause great financial disruption — fits the purpose of insurance as described in Chapter 1. But his description of when efficiency is achieved — when the highest possible welfare is produced for the insured — leaves open the question of who else’s welfare may be affected as a result.

The characteristics of the insurance coverage, such as cost sharing, can influence both distributional and medical efficiency. A study of physician prescribing shows how doctors take patients’ insurance status into consideration when they prescribe a biologic agent (DeWitt 2006). This study, conducted before implementation of the Medicare Part D drug benefit, found that patients with RA who were covered by government-sponsored insurance were 30 percent more likely
to receive a prescription for an infused agent than patients with commercial coverage. This may have been because Medicare covers the infused drug under Part B and that the physician, aware of the patient's benefits coverage, was doing the patient a financial favor by helping the patient avoid the out-of-pocket costs that would have been associated with a self-injectable medication in the same class. In this study, the self-administered drug was more often prescribed for patients with private insurance when the patient’s prescription drug plan covered that drug.

The same considerations that shaped physician decision making in the DeWitt study are applicable to a privately insured population. Benefit design and financial incentives can directly or indirectly promote the use of one drug over another, rather than allow for a choice based on expected clinical outcomes and/or cost efficiencies in its administration. Though this kind of decision making makes sense from the very narrow perspective of one physician interacting with one patient, it does not contribute to overall insurance efficiency. Benefit designs that yield value to purchasers and provide patients with appropriate access to care offer the greatest potential for insurance efficiency.

**Dynamic efficiency.** In the quest to contain short-term health care costs, dynamic efficiency may be overlooked because it drives long-term innovation. The popularity of a particular drug may generate the revenue needed to spur development of a more cost-effective version of that product or an entirely different drug.

The impediment to achieving full dynamic efficiency can be reduced to a simple concept: No one can predict the future. No one can say with certainty that money that appears to be inefficiently spent today will not lead, some day, to scientific advances that result in improved efficiency.

**Production efficiency.** Cancer is the second leading cause of health-related lost productivity in American business (DeVol 2007). Oncology is the most active area of biotech drug development with more than 200 therapies in various stages of development (PhRMA 2006). Some of the new oncologic products that will make it to market will be in oral formulation, as manufacturers respond to patient and payer demand for products that are more convenient to take, better tolerated, and amenable to management under the pharmacy benefit. Oral medications offer potential for reducing the cost to manufacture a biologic.

Many of the new oncologics introduced in the next decade will be aimed at specific groups of patients who, as identified by genetic diagnostic tests, will have the highest likelihood of benefitting from these products. Genetic tests — properly called molecular tests — could become an important tool for reducing the cost and time involved in developing a biologic and, ultimately, reducing its market cost.

As the sensitivity (ability to diagnose without “false negatives”) and specificity (ability to diagnose without “false positives”) of molecular tests improve, it is likely that more payers will require them before authorizing coverage of a biologic therapy. In return, drug manufacturers will be able to make credible claims about the likelihood of product efficacy, and thus, their medical efficiency and overall value.

**BFAC: OUR ANALYSIS**

Efficiency in the context of medical care is complex — even more so when high-stake biologics are added to the equation. Efficient management and administration of biologics requires heeding factors that affect not just one but all five types of efficiency that characterize health care. If you are designing insurance benefits for biologics, recognize that your view of one type of efficiency...
may affect the other types of efficiency. The same is true if you are making medical decisions about who gets biologics and for how long. As noted in chapter 2, value judgments differ among the various stakeholders, and these biases influence the degree of importance each stakeholder places on each type of efficiency.

Among the five types of efficiency, the characteristics that define medical efficiency often come to mind first when one is asked to describe efficiency in health care. Achieving medical efficiency is not a simple proposition. Providing a benefit the right drug for a specific patient, a choice made by evaluating its potential for effectiveness and tolerability against a patient's likelihood of response — and not solely on such black-and-white factors as acquisition price and how it is given to a patient — is critical for preventing progression of disease and managing the overall cost of care. This is the challenge of personalized medicine.

The cost and health threats posed by nonadherence to a therapeutic regimen intensify that challenge. Even among people who have life-threatening or chronic conditions, adherence declines sharply over time (Partridge 2003). Nonadherence has multiple causes. Some oral and self-injectable biologics have complicated dosing schedules that are difficult for patients to follow. Some patients may have physical limitations, such as joint deformity resulting from RA, that preclude self-administration. In the working population, an employee might find it difficult to take time off from work for regular infusions or injections.

Plan designs and policies that directly and indirectly promote adherence can yield medical and insurance efficiencies. The value of focusing on adherence is seen in the results of the Asheville Project, a 6-year effort in which copayments for patients with diabetes were waived in exchange for their commitment to regular consultations with a health care professional who helped them stay on their course of therapy. For every $1 spent on the program, employers saved $4 in reduced absenteeism and workers’ compensation claims (Heinze 2007).

A drug’s mode of administration is strongly linked to distributional efficiency, yet this should be only part of an overall strategy for the efficient management of biologics. Although it seems clear that a self-injected biologic agent would have less up-front cost, if a patient physically cannot administer the drug, it may not achieve efficiencies for either the payer or purchaser. On the other hand, an infused medication may not allow the patient to be maximally productive in the workplace. Too rigid a focus on distributional efficiency — the way a patient is given a drug — can decrease medical efficiency. This concept takes even greater importance at a time when increased demand for health care resources coincides with a weakening economy. Fewer dollars are available to support the increased demand for effective drugs. Efficiencies in the provision of expensive agents are intrinsically good for employees who need them and for society as a whole.

Ultimately, the way a drug is given to a patient may be rendered a crude tool for differentiating biologics; in the context of molecular tests that can identify a therapy with a high a priori likelihood of response, mode of administration could become of small consequence. In health care, it takes a new technology 15 years to become fully accepted, but the advent of $100,000-a-year drugs will hasten the adoption of molecular diagnostics (Carroll 2007). Payers and purchasers should support the development of technologies that can foster numerous efficiencies.

Because of the concepts underlying dynamic efficiencies, rational utilization of biologics may answer the question of whether access promotes the greatest possible welfare for a patient or advances the science. New drug discoveries, new de-
livery procedures, and new technologies are, in some part, a product of the U.S. health care system. For all of the faults of that system, Americans benefit from its reimbursement policies and regulations, which in the end, fund innovation.

Through this discussion of the types of efficiency in health care, we provide a road map for applying the concepts of value, access, and affordability discussed in previous chapters. Though biologics have elevated the standard of care for patients with diseases previously considered to be untreatable, each therapy’s value is in the eye of the beholder. The interests of physicians in maximizing their patients’ welfare, the strategic concerns of manufacturers, the business goals of employers, and the fiduciary responsibilities of payers, specialty pharmacies and PBMs all compete and dovetail at various junctures. Actions taken to achieve one type of efficiency will cause a reaction with respect to another. Real efficiency requires finding a balance, and that balance may differ from patient to patient.

Identifying health care interventions with high potential for health-status improvement in a patient or a population is a collaborative process that requires knowledge of the value of each intervention to each party. Mandates and indirect influences to compel usage of a specific therapy can be counterproductive if that product is ineffective in a given patient. A genuine desire to match patients with the right drug will yield benefit designs that make those interventions accessible. This provides the best hope for moving toward full efficiency.

References
CONTINUING MEDICAL EDUCATION ASSESSMENT/EVALUATION/CERTIFICATE REQUEST

Biologic Therapy Management: The Need for Value-Based Health Benefits Models

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Release Date: March 15, 2008
Expiration Date: March 15, 2009

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T7N39-MG

EXAMINATION: Place an X through the box of the letter that represents the best answer to each question on page 45. There is only ONE correct answer per question. Place all answers on this form.

A. B. C. D. E.
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PROGRAM EVALUATION

So that we may assess the value of this self-study program, we ask that you please fill out this evaluation form.

Have the objectives for the activity been met?

1. Define the societal issues pertinent to patient access to appropriate health care treatment options. □ Yes □ No

2. Evaluate the role and value of biologics for chronically ill patients. □ Yes □ No

3. Advocate for policies surrounding access to, reimbursement for, and financing of biologics. □ Yes □ No

Was this publication fair, balanced, and free of commercial bias? □ Yes □ No

If no, please explain: ____________________________________________________________

____________________________________________________________________________

____________________________________________________________________________

____________________________________________________________________________

Please use the following scale to answer the next four questions:

Strongly Agree............5
Agree.................................4
Neutral.............................3
Disagree...........................2
Strongly Disagree........1

Did this educational activity meet my needs, contribute to my personal effectiveness, and improve my ability to:

Treat/manage patients?
5 4 3 2 1 N/A

Communicate with patients?
5 4 3 2 1 N/A

Manage my medical practice?
5 4 3 2 1 N/A

Other ______________________________

5 4 3 2 1 N/A

Effectiveness of this method of presentation:

Very
Excellent good Good Fair Poor
5 4 3 2 1

What other topics would you like to see addressed? __________________________________

____________________________________________________________________________

____________________________________________________________________________

Comments: ________________________________________________________________

____________________________________________________________________________

____________________________________________________________________________
CONTINUING EDUCATION POST-TEST
Biologic Therapy Management: The Need for Value-Based Health Benefits Models

Please tear out the assessment/evaluation form on page 44. On the answer sheet, place an X through the box of the letter corresponding to the correct response for each question. There is only one correct answer to each question.

1. What is the fundamental purpose of health insurance?
   a. Protect the insured against a catastrophic health event.
   b. Maintain an acceptable health care level for the insured.
   c. Keep risk low for the insurer.
   d. Subsidize the health care of non-insured people.

2. According to The Zitter Group, the average cost share for biologics ($ copayment, % co-insurance) in late 2007 was:
   a. $44, 10%.
   b. $44, 22%.
   c. $88, 10%.
   d. $88, 22%.

3. Among payers and purchasers, a primary objection to randomized controlled clinical trials is that they:
   a. Have no real-world relevance.
   b. Lack methodological rigor.
   c. Are expensive to conduct.
   d. Answers a and c.

4. What did the Rand Health Insurance Experiment demonstrate?
   a. Patients will seek medical care regardless of cost.
   b. Demand for care is elastic: The less a family pays, the more services it uses.
   c. Cost sharing promotes the use of effective health services.
   d. Growth of health care expenditures stems from consumption of excess marginal care.

5. Studies document that high cost sharing reduces health care utilization. Which of the following is/are true?
   a. Reduced utilization has little effect on healthy people, but outcomes are poorer for those at higher medical risk.
   b. Cost-cutting techniques are counter-intuitive when applied to drugs for which patients perceive a strong need.
   c. Drug copayments and coinsurance generally count toward out-of-pocket annual maximums, reducing concerns about access to biologics.
   d. All of the above.
   e. Answers a and b only.

6. True or false: A rigid focus on a single type of health care efficiency decreed by Aaron (2005) should have no measurable consequences on the overall efficiency of a biologics management strategy.
   a. True.
   b. False.

7. By 2013, the share of drug spending attributable to biologics will be:
   a. 1 percent.
   b. 25 percent.
   c. 37 percent.
   d. More than 50 percent.

8. Moral hazard refers to the insurance principle that says:
   a. People without health insurance endanger the lives of those who have it.
   b. People who have health insurance will use more health care services.
   c. People with health insurance will demand coverage of lifestyle drugs.
   d. The cost of employee health insurance is offset by lower wages.

9. Value-based benefit design holds that:
   a. Patients with chronic conditions should receive rebates for filling prescriptions.
   b. Patients with chronic conditions might be able to avoid expensive downstream care if medications are made available to them at little or no cost.
   c. Life-saving drugs should be placed on the lowest pharmacy tier and lifestyle drugs on the highest.
   d. Benefit plan design should mirror National Committee for Quality Assurance HEDIS recommendations.

10. Economic analyses are used to determine the value of a health care intervention:
    a. To assess which intervention would be the least costly to the insurer.
    b. To assess which intervention will be most clinically effective for the patient.
    c. To reconcile subjective or disparate determinations of an intervention’s value.
    d. So that an economic value can be applied to clinical trial results.

11. Molecular tests, also known as genetic tests:
    a. Have the potential to predetermine the clinical value of a biologic therapy.
    b. Could eventually reduce biologics’ research and development costs, and ultimately, cost to employers.
    c. Are widely supported by payers and employers.
    d. All of the above.
    e. Answers a and b.

12. In the first year it tried a value-based benefit design, Pitney Bowes saved in cost offsets:
    a. $500,000.
    b. $1 million.
    c. $5 million.
    d. Nothing; ER visits decreased but drug expenditures increased.

13. Nyman (2003) argues that an optimally designed insurance policy would:
    a. Use cost sharing to control inefficient moral hazard.
    b. Use cost sharing to control all moral hazard.
    c. Be based on moral hazard profiles for specific illnesses.
    d. Answers a and c.
    e. Answers b and c.

14. Characteristics of a patient’s insurance coverage can influence distributional and medical efficiencies. Which of the following is true in that regard?
    a. Benefit design and financial incentives can promote prescribing of one biologic over another.
    b. Designating a preferred biologic promotes distributional efficiency.
    c. Benefit design and cost sharing are more important to distributional efficiency than to medical efficiency.
    d. Designating a preferred biologic promotes medical efficiency.

15. True or False: The top seven chronic conditions in the United States costs employers $100 billion annually.
    a. True.
    b. False.

16. Why is rheumatoid arthritis important to employers?
    a. It emerges during middle age.
    b. It leads to high rates of absenteeism and disability.
    c. It is associated with serious concomitant health conditions.
    d. All of the above.

17. On average, what share of a health plan’s members use specialty drugs?
    a. 1 to 3 percent.
    b. 1 to 5 percent.
    c. 5 to 10 percent.

18. An economic perspective of corporate health benefits holds that employers offer health insurance primarily to:
    a. Improve productivity.
    b. Keep wages low.
    c. Meet employee demand for health care.
    d. Compete in the marketplace.

19. By 2011, per-member, per-month (PMPM) spending for biologics is expected to be:
    a. $9.80.
    b. $3.00.
    c. $5.00.
    d. More than $9.80.

20. Why is adherence to a biologic treatment regimen important to efficiency?
    a. Plan designs that directly and indirectly promote adherence can yield medical and insurance efficiencies.
    b. A patient’s inability to follow a dosing regimen, administer a self-injectable, or take time from work for regular infusions can lead to medical inefficiency.
    c. Mode of administration is strongly linked to distributional efficiency, but the designation of preferred biologics may introduce barriers to adherence.
    d. All of the above.